Whitney E. Street (CA Bar No. 223870)
BLOCK & LEVITON LLP
100 Pine Street, Suite 1250
San Francisco, CA 94111
Tel.: (415) 968-1852
wstreet@blockesq.com

Stephen J. Teti (*pro hac vice motion forthcoming*)
BLOCK & LEVITON LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
Tel.: (617) 398-5600
steti@blockesq.com

Counsel for Plaintiff

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CITY OF PROVIDENCE, individually and on behalf of all others similarly situated,
Plaintiff,

v.

BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC., LUPIN LTD., and PDL BIOPHARMA, INC.,

Defendants

Case No. _____

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff City of Providence ("Plaintiff"), on behalf of itself and all others similarly situated, files this Class Action Complaint against Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International, Inc.), Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., Santarus, Inc., Assertio Therapeutics, Inc. (formerly known as Depomed, Inc.), Lupin Pharmaceuticals, Inc., Lupin Ltd. (with Lupin Pharmaceuticals, Inc., "Lupin"), and PDL BioPharma, Inc. (collectively "Defendants"). Plaintiff's claims arise from Defendants' anticompetitive scheme to restrain competition in the market for Glumetza® and its AB-rated generic equivalents sold in the United States. Plaintiff's allegations are made based on personal knowledge as to itself and upon information and belief as to all other allegations. Plaintiff alleges as follows.

I. NATURE OF THE ACTION

1. Plaintiff seeks damages and equitable relief arising from Defendants' anticompetitive misconduct, which eliminated generic competition in the United States for branded and generic versions of Glumetza (metformin hydrochloride extended release). Glumetza is a drug used to treat patients with Type 2 diabetes.

2. Prescription metformin has been available as a generic drug since 2002. Patients with Type 2 diabetes use metformin to prevent and control high blood sugar, helping the body to properly respond to its own naturally produced insulin. A person with Type 2 diabetes who fails to control high blood sugar can develop very serious disabilities, such as kidney damage, blindness, and loss of limbs or sexual function.

3. Defendant Assertio developed an extended-release version of metformin that can alleviate some of the drug's common side effects. Assertio obtained several patents on the extended-release technology.

4. In 2005, Assertio received approval from the United States Food and Drug Administration (the "FDA") to sell, and began selling, extended-release metformin, marketed under

the brand name Glumetza, in two sizes: 500 mg and 1,000 mg. Extended-release mechanisms are very common, however, and Assertio's patents[1] were invalid and could be designed around.

5. After Glumetza launched, its sales grew rapidly. As of 2016, Valeant's U.S. sales of Glumetza exceeded $1.2 billion annually.

6. Because Glumetza was a blockbuster drug, several generic manufacturers filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking the approval of generic versions of Glumetza. Specifically, at least Lupin, Sun Pharmaceuticals,[2] and Watson Pharmaceuticals[3] filed ANDAs with the FDA concerning proposed generic versions of Glumetza. Lupin was the first generic manufacturer to file an ANDA concerning Glumetza.

7. The effects of generic competition for a brand drug are predictable: sales switch quickly from the more expensive brand drug to the generic version, causing brand manufacturers' profits to fall dramatically upon generic entry. Generic drugs are priced at a fraction of the brand drug price, with prices for the generics falling further as additional generics enter the market. Preventing and/or delaying generic entry is therefore a highly profitable (albeit unlawful) goal for brand manufacturers and results in substantial overcharges to patients and third party payors.

8. As part of their applications, these would-be generic manufacturers were required to make certain certifications against the patents covering Glumetza. Lupin, Sun, and Watson all filed what are known as "Paragraph IV Certifications," made under 21 U.S.C. §355(j)(2)A)(vii), which certify that the patent(s) asserted by Assertio are either "invalid or will not be infringed by the generic manufacturer's proposed product."

---

[1] Assertio listed 4 patents on the 500 mg formulation (U.S. Patent Nos. 6,488,962 (the "962 Patent") that expires on June 20, 2020; 6,723,340 (the "340 Patent") that expires on Oct. 25, 2021, 6,340,475 (the "475 Patent") that expired on Sep. 16, 2016; and 6,635,280 (the "280 Patent") that expired on Sep. 16, 2016)). Assertio listed 3 patents on the 1,000 mg formulation (U.S. Patent Nos. 7,780,987 (the "987 Patent") that expires on Mar. 23, 2025; 8,323,692 (the "692 Patent") that expires on Mar. 23, 2025; and the '962 Patent.

[2] Pharma Global FZE, Sun Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Inc. (collectively, "Sun").

[3] Watson Laboratories, Inc.—Florida, Watson Pharmaceuticals, Inc., and Watson Pharma, Inc. (collectively, "Watson").

9. Defendant Assertio[4] and its marketing partner, Santarus, sued each generic manufacturer that filed an ANDA for allegedly infringing Assertio's Glumetza patents.

10. Assertio and Santarus' patent infringement lawsuit against Lupin (the first ANDA filer) triggered an automatic prohibition on Lupin's entry into the market for 30 months. Just before that 30-month period was set to expire (and Lupin was set to enter the market with generic Glumetza), Assertio/Santarus and Lupin settled the patent infringement litigation.

11. The settlement, reached in February 2012, includes what amounts to a "pay for delay" (also known as a "reverse payment") agreement. Pursuant to the agreement, Lupin agreed to stay out of the market for Glumetza for four additional years, meaning that there would be no generic competition for the drug until February 2016. In exchange, Assertio and Santarus agreed that when Lupin did finally enter the market in 2016, for at least 180 days, Assertio and Santarus would not compete against Lupin by marketing their own authorized generic version of Glumetza.

12. In other words, these Defendants allocated the market for Glumetza between them. Assertio and Santarus held the entire market from February 2012 through February 2016, while Lupin exclusively held the generic portion of the market from February 2016 through at least August 2016 (and in fact, until February 2017). Such an agreement represents a blatant violation of antitrust law.

13. Other generic manufacturers – specifically Sun and Watson – could have upended this anticompetitive scheme. The weakness of Assertio's patents created the risk that another manufacturer could invalidate them (or demonstrate that its product would not infringe those patents) and market a generic Glumetza product before February 2016. To prevent that possibility, Assertio/Santarus and Lupin included in their agreement two deterrent provisions aimed at other competitors. First, Assertio/Santarus agreed that, if another generic manufacturer succeeded in entering the market before February 2016, Lupin could also enter on that earlier date. Second, Assertio/Santarus agreed that they would not grant a license to any other would-be generic

[4] Assertio was known as Depomed, Inc. until August 2018.

manufacturer to enter the market until at least 180 days after Lupin entered the market with its generic product.

14. These two provisions ensured that, no matter how many resources another would-be generic manufacturer might expend in working to overcome Assertio's patents, it could never get the financial reward of being the only generic manufacturer on the market. It could not get that reward by winning a patent lawsuit against Assertio/Santarus (since the first deterrent provision would allow Lupin to enter earlier); and it could not get that reward by negotiating an earlier-entry license from Assertio/Santarus (since the second deterrent provision expressly prohibited such a license).

15. Assertio/Santarus and Lupin unlawfully closed every pathway to generic competition before February 2016. Lupin agreed not to enter before then, and the deterrents eliminated the incentive for other generic manufacturers to try to enter before then. Moreover, these Defendants extended the anticompetitive effect beyond February 2016, since Assertio and Santarus agreed that they would not compete in the generic sector from February 2016 until at least August 2016 (and in fact did not launch an authorized generic version of Glumetza until February 2017), and agreed not to grant a license to any other generic to compete during that time.

16. In short, Assertio/Santarus and Lupin engaged in an anticompetitive scheme to monopolize the sale of Glumetza and its generic equivalents where, under lawful, competitive practices, a monopoly should not, and would not, have existed.

17. This monopoly was wildly profitable, and Assertio/Santarus wasted no time in exploiting it. In October 2013, Assertio sold its royalties for Glumetza to PDL Biopharma, Inc. as part of a purchase agreement payment totaling $240.5 million. In November 2013, Santarus announced that it was being acquired by Defendant Salix for $2.6 billion. At the time, Glumetza accounted for just under half of Santarus' sales. From 2012 to 2015, Glumetza prices rose by over 40%, far exceeding the 4.2% rise in the Consumer Price Index.

18. Then in April 2015, when Glumetza accounted for more than 25% of its sales, Salix in turn sold the Glumetza monopoly to Valeant Pharmaceuticals, Inc. (now Defendant Bausch). Valeant paid $14.5 billion to acquire Salix.

19. Valeant is known industrywide as a recidivist exploiter of drug product monopolies. As *Forbes* magazine has characterized it, Valeant's business strategy "emphasized boosting drug prices, gutting research and development budgets, [and] firing employees . . . ."[5] "Scientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary." Industry observers concluded that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned."[6]

20. Within just four months of acquiring the Glumetza monopoly, ***Valeant raised the price an additional 750%***. The price of a 30-day supply of the 1,000 mg product skyrocketed from $350 to more than $3,000. In the six months before the price hike, Salix made $145 million on Glumetza; in the half year after, Valeant made more than $800 million.

21. Furthermore, Defendants' anticompetitive misconduct also resulted in an outrageously high price for the generic product when Lupin finally entered the market in February 2016. Valeant complied with the unlawful agreement not to compete in the generic sector, and Lupin took full advantage. Without any generic competition, and with branded Glumetza being sold at an astronomically high price, Lupin sold a 30-day supply of the 1,000 mg formulation of generic Glumetza for over $2,200. Lupin made more than $650 million in profits on generic Glumetza in 2016 alone.

22. Fair competition would have curtailed the price of a 30-day supply of both branded and generic Glumetza. Instead, Defendants were able to charge over $3,000 for the brand version and over $2,200 for the generic version. Plaintiff alleges that Defendants' blatant violation of federal and state laws allowed them to drastically overcharge class members for Glumetza.

23. On behalf of itself and all other indirect purchasers of brand and generic Glumetza, Plaintiff brings this lawsuit to recover damages for these overcharges and to obtain such equitable relief as the Court may deem appropriate.

---

[5] Nathan Vardi & Antoine Gara, Valeant Pharmaceuticals' Prescription for Disaster, *Forbes*, April 13, 2016, https://www.forbes.com/sites/nathanvardi/2016/04/13/valeantpharmaceuticals-prescription-for-disaster/#6f4f657f206c.

[6] Bethany McLean, The Valeant Meltdown and Wall Street's Major Drug Problem, *Vanity Fair*, Summer 2016, https://www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem.

II. JURISDICTION AND VENUE

24. This Court has jurisdiction under 28 U.S.C. §§1331 and 1337 because this action seeks injunctive and equitable relief under the Clayton Act, 15 U.S.C. §26. This Court also has jurisdiction under §12 of the Clayton Act, 15 U.S.C. §22.

25. This Court also has jurisdiction under 28 U.S.C. §1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed Damages Class exceeds $5,000,000, and at least one member of the Damages Class is a citizen of a state different from that of one of the Defendants. This Court also has supplemental jurisdiction over state law claims under 28 U.S.C. §1367(a).

26. Venue is appropriate in this District under 15 U.S.C. §§15(a) and 22, and 28 U.S.C. §1391(b). Defendants transact business, are found, or have agents within this District, and a portion of the affected interstate trade and commerce discussed herein was carried out in this District. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District. Moreover, the effects of Defendants' conduct on interstate trade or commerce are ongoing.

27. This Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of causing injury to, persons residing in, located in, or doing business throughout the United States, including in this District.

III. INTRADISTRICT ASSIGNMENT

28. Pursuant to Local Rule 3-2(c), this is an Antitrust Class Action to be assigned on a district-wide basis.

IV. PARTIES

29. Plaintiff City of Providence is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. City of Providence is a self-insured health and welfare benefit plan that provides reimbursement for some or all of the purchase price of prescription drugs, including Glumetza and its generic equivalents. City of Providence provided reimbursement for

some or all of the purchase price of Glumetza and/or its generic equivalents for its active and retired public employees and their dependents in Rhode Island and other States. City of Providence suffered injury as a result of Defendants' unlawful conduct.

30. Defendant Assertio Therapeutics, Inc. ("Assertio") is a corporation organized under the laws of Delaware with its principal place of business located at 100 South Saunders Road, Suite 300, Lake Forest, Illinois. Until August 14, 2018, Assertio was named Depomed, Inc., which was a party to the unlawful agreements alleged herein. Assertio is the owner or licensee of the relevant patents.

31. Defendant Santarus, Inc. ("Santarus") is a corporation organized under the laws of Delaware with a principal place of business located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Pursuant to a Commercialization Agreement signed in August 2011, Assertio granted Santarus exclusive rights to manufacture and commercialize Glumetza in the United States. Santarus was a party to the unlawful agreements alleged herein. On January 2, 2014, Santarus was acquired by Defendant Salix Pharmaceuticals, Ltd. and became a wholly owned subsidiary of Salix Pharmaceuticals, Inc.

32. Defendant Salix Pharmaceuticals, Inc. is a corporation organized under the laws of California with its principal place of business located at 400 Somerset Corporate Blvd. Bridgewater, New Jersey 08807. Salix Pharmaceuticals, Inc. joined and adhered to the unlawful agreements alleged herein. Salix Pharmaceuticals, Inc. is a wholly owned subsidiary of Salix Pharmaceuticals, Ltd.

33. Defendant Salix Pharmaceuticals, Ltd. is a corporation organized under the laws of Delaware with its principal place of business located at 400 Somerset Corporate Blvd. Bridgewater, New Jersey 08807. Effective January 1, 2014, Salix Pharmaceuticals, Inc. and Salix Pharmaceuticals, Ltd. (together, "Salix") assumed Santarus' rights and obligations under its Commercialization Agreement with Assertio. Salix Pharmaceuticals, Ltd. joined and adhered to the unlawful agreements alleged herein.

34. On April 1, 2015, Salix was acquired by Valeant Pharmaceuticals International, Inc. ("Valeant"), which, on or about that date, assumed Santarus' and Salix's rights and obligations

under the Commercialization Agreement with Assertio. Valeant joined and adhered to the unlawful agreements alleged herein. Effective July 13, 2018, Valeant changed its corporate name to Bausch Health Companies Inc. Salix Pharmaceuticals, Ltd. is now a wholly owned subsidiary of Bausch Health Companies Inc.

35. Defendant Bausch Health Companies Inc. ("Bausch") is a corporation organized and existing under the laws of British Columbia, Canada, with its U.S. headquarters located at 400 Somerset Corporate Blvd. Bridgewater, New Jersey 08807. Bausch joined and adhered to the unlawful agreements alleged herein.

36. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia with its principal place of business located at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals is a wholly owned subsidiary of Defendant Lupin Ltd. and was a party to the unlawful agreements alleged herein.

37. Defendant Lupin Ltd. is a company organized under the laws of India with its principal place of business located at B/4 Laxami Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051, India, and was a party to the unlawful agreements alleged herein.

38. Lupin Pharmaceuticals, Inc. and Lupin Ltd. are collectively referred to herein as "Lupin."

39. Defendant PDL BioPharma, Inc. ("PDL") is a corporation organized under the laws of Delaware with its principal place of business located at 932 Southwood Boulevard, Incline Village, Nevada 89451. In October 2013, Defendant Assertio sold its royalties for Glumetza to PDL.

40. To avoid any confusion, as there are numerous parties relevant to this lawsuit:

a. Defendant Assertio was formerly named Depomed, but is referred to herein under its current name, Assertio;

b. Assertio sold its royalties for Glumetza to PDL in October 2013;

c. Assertio was the original owner/licensee of the germane Glumetza patents;

d. In August 2011, Assertio entered into a Commercialization Agreement with Santarus that granted Santarus exclusive rights to manufacture and commercialize Glumetza in the United States;

e. In January 2014, Salix acquired Santarus, and Santarus became a wholly-owned subsidiary of Salix;

f. In April 2015, Valeant acquired Salix and assumed Santarus' and Salix's rights and obligations under the Commercialization Agreement with Assertio;

g. Valeant subsequently changed its name to Bausch Health Companies, Inc.; and

h. Salix Pharmaceuticals, Ltd. is now a wholly owned subsidiary of Bausch.

41. All of Defendants' actions described in this Class Action Complaint are part of, and in furtherance of, the unlawful conduct alleged herein. These actions were authorized, ordered, or undertaken by Defendants' various officers, agents, employees, or other representatives while engaged in the management of Defendants' affairs (or those of their predecessors-in-interest) within the course and scope of their duties and employment or with the actual, apparent, and/or ostensible authority of Defendants.

V. FACTUAL ALLEGATIONS

a. Characteristics of the Pharmaceutical Marketplace

42. The marketplace for the sale of prescription pharmaceutical products in the United States contains a significant feature that can be exploited by manufacturers to extend a monopoly in the sale of a particular pharmaceutical composition. In most industries, the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

43. The pharmaceutical marketplace, by contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Glumetza, to patients without a prescription written by the patient's physician. The prohibition on dispensing certain products without a

prescription introduces a "disconnect" in the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

44. Many pharmaceutical manufacturers, including Defendants, exploit this feature of the pharmaceutical marketplace. The so-called "brand manufacturers" (*i.e.*, the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices to persuade physicians to prescribe the manufacturer's products. Importantly, these detailers do not advise the physicians of the cost of the branded products. Studies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, because they do not pay for the products themselves. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

45. In situations where two manufacturers each sell a drug that serves a similar medical function and each manufacturer uses a significant detailer force, those products are often sold at very similar, high prices, thus eliminating any consumer benefit from that "competition." This is in stark contrast to the situation in which the competing seller of an AB-rated, bioequivalent drug is a generic company without a detailer force. In that case, the generic price is significantly lower than the brand price, and consumers benefit as Congress had intended by enacting the Hatch-Waxman Act, discussed below.

46. When the relative importance of the price between two branded pharmaceuticals, or pharmaceuticals that otherwise are not AB-rated to one another, is low, the price elasticity of demand — the extent to which sales go down when price goes up — is by definition also low, which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales. The ability to raise price above competitive levels without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly power.

47. Congress sought to ameliorate the "disconnect," and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed below. When a pharmacist receives a prescription for a branded pharmaceutical product, and an AB-rated generic version of that product is available, state laws permit (or in some cases require) the pharmacist to dispense the generic product in lieu of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is ameliorated between the AB-rated generic product and the corresponding branded product. When an AB-rated generic product is introduced and is not prevented from competing unfettered, branded pharmaceutical manufacturers are no longer able to exploit the features of the pharmaceutical industry, their monopoly power dissipates, and some of the normal competitive pressures are restored.

48. If Defendants' unlawful conduct had not prevented generic manufacturers from successfully entering the market with generic versions of Glumetza, end-payors like Plaintiffs and members of the Classes would have saved millions, if not billions, of dollars in purchases. Defendants' anticompetitive scheme purposely manipulated generic competition to Glumetza.

b. Regulatory and Economic Background

i. Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

49. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), branded drug manufacturers must obtain FDA approval to sell a new drug product by filing a New Drug Application ("NDA"). 21 U.S.C. §§301–392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §355(a), (b).

50. When the FDA approves a branded drug manufacturer's NDA, the manufacturer may list in the Orange Book any patents the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the branded drug before the expiration of the listed patents. The branded drug manufacturer may also list in the

Orange Book any patents issued after the FDA approved the NDA within thirty days of their issuance. 21 U.S.C. §355(b)(1), (c)(2).

51. The FDA relies completely on a branded drug manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to verify a branded drug manufacturer's patents and patent information for accuracy or trustworthiness. In listing patents and patent information in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

52. Enacted in 1984, the Hatch-Waxman Act simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in a branded drug manufacturer's original NDA, but must further show that the generic drug: (i) contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug; and (ii) is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

53. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drugs containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as its branded counterpart. 21 U.S.C. §355(j)(8)(B).

54. Congress enacted the Hatch-Waxman Act to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

55. The Hatch-Waxman Act achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for branded drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total annual prescription drug revenue had soared to $300 billion.

2. Paragraph IV Certifications

56. Where the NDA holder has submitted patent information describing a listed patent as claiming a relevant drug substance or drug product, an ANDA applicant must certify that the generic drug will not infringe those patents. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications, that:

a. no patent for the branded drug has been filed with the FDA (a "Paragraph I certification");

b. the patent for the branded drug has expired (a "Paragraph II certification");

c. the patent for the branded drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. the patent for the branded drug is invalid or will not be infringed by the generic drug manufacturer's proposed product (a "Paragraph IV certification").

57. If a generic drug manufacturer files a Paragraph IV Certification, a branded drug manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic drug manufacturer filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months; or (b) the issuance of a decision by a court that the

patent is invalid or not infringed by the generic drug manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic drug manufacturer to market its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

58. The high profit margins on brand drugs and the predictable effects of generic entry—sales switch quickly from the brand to the generic—create powerful financial incentives for brand manufacturers to sue any generic competitor that files an ANDA with a Paragraph IV certification, even if the competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable. By simply listing the patents in the Orange Book and filing the lawsuit, the brand manufacturer can delay final FDA approval of an ANDA for up to 30 months.

59. As an incentive to generic drug manufacturers to seek approval of generic alternatives to branded drugs, the first generic drug manufacturer to file an ANDA containing a Paragraph IV Certification typically receives a period of protection from competition from other generic versions of the drug. For Paragraph IV Certifications made before December 8, 2003, the first generic drug manufacturer applicants received 180 days of market exclusivity, which could not be forfeited and was triggered only by commercial marketing of the generic product. For Paragraph IV Certifications made after December 8, 2003, the first generic drug manufacturer applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means the first approved generic drug is the only available generic drug for at least six months.

60. Branded drug manufacturers can "game the system" by describing patents as containing relevant drug product claims (even if the patents, in fact, do not do so) and suing any generic drug manufacturer competitor filing an ANDA with a Paragraph IV Certification (even if the competitor's product does not actually infringe the listed patents) to delay final FDA approval of an ANDA for up to 30 months. Branded drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay generic drug competition—as opposed to enforcing a valid patent that is actually infringed by the generic drug either by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal of the suit.

61. For Paragraph IV Certifications made before December 8, 2003, the first generic drug manufacturer applicant could help a branded drug manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic drug manufacturers. The first generic drug manufacturer applicant, by agreeing not to begin marketing its generic drug, thereby could delay the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic created a "bottleneck" because later generic drug manufacturer applicants could not enter the market until the first generic drug manufacturer applicant's 180-day exclusivity had elapsed.

62. On December 8, 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") to make it more difficult for branded drug and generic drug manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines several conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic drug products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

63. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV Certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

64. Branded drug manufacturers and first-filing generic drug manufacturers can structure their settlements in order to intentionally skirt the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first

applicant submitted a Paragraph IV Certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV Certification were invalid or not infringed. When that happens, to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic drug manufacturer filed Paragraph IV Certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the branded drug manufacturer did not assert against it in a Paragraph IV Litigation.

3. The Benefits of Generic Drugs

65. Generic versions of branded drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective, as their branded counterparts. In particular, generic drugs that are pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to their brand-name counterparts are given an "AB" rating by the FDA. Pharmacists substitute an AB-rated generic product for the corresponding brand-name product unless the doctor has indicated that the prescription for the brand-name product must be dispensed as written.

66. In the absence of generic competition, brand manufacturers can usually sell the brand drug far above the marginal cost of production, generating profit margins in excess of 70% (and sometimes up to 98%) while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power.

67. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics accelerates. The only material difference between generic drugs and branded drugs is their price: generic drugs are usually at least 25% less expensive than their branded drug counterparts when there is a single generic drug competitor. The discount typically increases to 50% to 80% (or more) when there are multiple generic drug manufacturer competitors in the market for a given branded drug. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The United States Federal Trade Commission ("FTC") conservatively estimates that, about one year after market

entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. When multiple generics are on the market, competition between them drives their prices to near the marginal cost of production. As a result, competition from generic drugs is viewed by branded drug manufacturers, such Defendants Assertio, Santarus, Salix, Bausch, and PDL, as a grave threat to their bottom lines.

68. Due to the price differentials between branded and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the branded drug. Since passage of Hatch-Waxman, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

69. There is an incentive to choose the less expensive generic drug equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generic drugs than on branded drugs. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic drugs for more expensive branded drugs. Health insurers are contractually obligated to pay for the bulk of their insureds' prescriptions, whether filled with branded drugs or generic drugs, so they offer lower copays for generic drugs in order to encourage their use.

70. Until the generic version of a branded drug enters the market, however, there is no bioequivalent generic drug to substitute for, and compete with, the branded drug, and, therefore, the branded drug manufacturer can continue to profitably charge supracompetitive prices. As a result, brand drug manufacturers, such as Defendants Assertio, Santarus, Salix, Bausch, and PDL, which are well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the introduction of generic drug competition into the market.

71. The 180-day marketing exclusivity to which first-filer generic drug manufacturers may be entitled does not prevent a branded drug manufacturer from marketing its own generic drug alternative to the branded drug during the 180-day period. Such an "authorized generic" is

chemically identical to the branded drug, but is sold as a generic drug through either the branded manufacturer's subsidiary (if it has one) or through a third-party generic drug manufacturer. Competition from an authorized generic drug during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

72. In its study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the FTC found that authorized generic drugs capture a significant portion of sales, reducing the first-filer generic drug manufacturer's revenues by approximately half on average during the 180-day exclusivity period. The first-filing generic drug manufacturer makes significantly less money when it faces competition from an authorized generic because: (i) the authorized generic drug takes a large share of unit sales away from the first filer; and (ii) the presence of an additional generic drug in the market causes prices to decrease.

73. Although first-filing generic drug manufacturers make significantly less money when they must compete with an authorized generic drug during the first 180 days, consumers and other drug purchasers, such as Plaintiffs and members of the putative Classes, benefit from the lower prices caused by competition between the authorized generic drug manufacturer and the first-filing generic drug manufacturer.

74. Given the significant negative impact of an authorized generic drug manufacturer on the first-filing generic drug manufacturer's revenues, a branded drug manufacturer's agreement not to launch an authorized generic drug has tremendous monetary value to the generic drug manufacturer. Branded drug manufacturers have used such agreements to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers, such as Plaintiffs and members of the putative Classes, of the lower prices resulting from two forms of competition: (i) between the branded drug and the generic drug; and (ii) between the generic drugs.

ii. Motive for and Methods of Conspiracy

75. To avoid the loss of profits when generics, especially multiple generics, come to market, the brand and generic manufacturer may agree not to compete, and instead, divide the market among themselves. For this to work, however, the generic manufacturer would need to

somehow share in the brand manufacturer's ill-gotten gains. Such pay-off deals are often referred to as "reverse payment," "exclusion payment," or "pay-for-delay" agreements.

76. Often it is only necessary for the brand manufacturer to pay off the first-filing would-be generic manufacturer (the first generic manufacturer to have included a Paragraph IV certification in its ANDA). The first filer's agreement to delay marketing its drug may also prevent other generic manufacturers from marketing theirs. If the first filer is eligible for 180 days of ANDA exclusivity, and does not forfeit it, no other generic manufacturer can enter the marketplace until the end of the ANDA exclusivity period. In that circumstance, the brand manufacturer needs only to pay off the first-filing generic to delay all generic competition.

1. No-AG Payments

77. In the 1990s, unlawful pay-offs by brand manufacturers to would-be generic competitors took the form of cash payments. As a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand and generic manufacturers making and receiving pay-offs became more sophisticated.

78. One of the more sophisticated – and anticompetitive – forms of payoff is a no-authorized generic agreement ("No-AG Agreement"). Pursuant to a No-AG Agreement, the brand manufacturer agrees not to market an authorized generic version of the drug until after a period of time – sometimes 180 days, often longer – following the first filer's market entry. In exchange, the would-be generic manufacturer agrees to delay entering into the market to compete against the branded drug. Each competitor reciprocally, *i.e.*, mutually, agrees to restrict its competition against the other.

79. As alleged *supra*, nothing about the generic first filer's 180-day period of ANDA exclusivity prohibits the brand manufacturer from marketing its NDA-based authorized generic during the 180 days. The Hatch-Waxman Amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based authorized generic.

80. Again, absent a No-AG Agreement, it almost always is financially advantageous for the brand manufacturer to begin marketing an authorized generic as soon as (or even before) the first generic manufacturer enters the marketplace.

81. Competition from an authorized generic drastically reduces the generic first filer's revenue, typically cutting it by at least half. The competing authorized generic takes a substantial volume of the unit sales and drives prices lower—all to the benefit of drug purchasers.

82. In exchange for an agreement from the brand manufacturer not to market an authorized generic that would cause this substantial loss of revenue and profit, a generic first filer may be willing to agree to delay its entry into the marketplace. The additional profits that the brand manufacturer gains from the delayed onset of generic competition more than make up for the profits that it forgoes by not competing with an authorized generic.

83. The brand manufacturer gains from the delayed onset of generic competition. The first filing would-be generic manufacturer gains from the absence of generic competition after it finally does enter the market. And drug purchasers lose three times over: first by the delay in the onset of the first filer's entry into the market; second, by the absence of authorized-generic competition once the first filer finally enters; and third, by the "bottleneck" that the first filer's delayed entry causes—absent forfeiture of the first filer's ANDA exclusivity, later-filing generic manufacturers cannot enter the market until the expiration of the first filer's artificially delayed ANDA Exclusivity period.

2. The Value of a No-AG Agreement to the Generic Manufacturer

84. A No-AG Agreement is extremely valuable to the first filing generic manufacturer. The first filer often earns the vast majority of all profits it will ever make on the drug—as much as 80% of all that it will ever make—during the 180-day period of generic exclusivity. It is almost always more lucrative for the first filing generic manufacturer to have 180 days on the market as the only generic than to enter the market earlier and compete against an authorized generic. Accordingly, the first filer is often willing to agree to later entry in exchange for a No-AG Agreement.

85. The Supreme Court has recognized that 180 days of generic exclusivity "can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.[7] And because an authorized generic can reduce the value of that exclusivity by 50% on average, a "no-AG agreement . . . may be of great value to . . . the first-filing generic."[8] "[N]o-AG agreements are likely to present the same types of problems as reverse payments of cash."[9] As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."[10]

86. The value of No-AG Agreements typically exceed the value that the first filing generic manufacturer could have obtained even if it had defeated the brand manufacturer's patent infringement lawsuit. The Hatch-Waxman Amendments provide the first filer a period of 180 days of ANDA exclusivity for winning patent infringement litigation. Importantly, however, the statute does not prevent the brand manufacturer from marketing an authorized generic during that time. By settling the patent case in exchange for a No-AG Agreement, the first filer converts that six months into a period of total generic exclusivity, in which it will not have to compete with an authorized generic.

---

[7] *FTC v. Actavis, Inc.,* 570 U.S. 136, 143 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem,* 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

[8] *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.,* 791 F.3d 388, 404 (3d Cir. 2015).

[9] *Id.*

[10] Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics (June 2009), http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf.

3. The Value of a No-AG Agreement to the Brand Manufacturer

87. No-AG Agreement are also extremely valuable to the brand manufacturer for one primary reason: they delay generic entry, perpetuating the brand manufacturer's monopoly. In other words, the brand manufacturer agrees to forego selling an authorized generic version during the first-filing generic manufacturer's 180-days of ANDA exclusivity (to the generic's benefit) in exchange for what often amounts to years of additional time to sell its brand product only, free from the threat of generic competition.

iii. Later-Filing Generic Manufacturers

88. In a settlement with a first-filing generic manufacturer, the brand manufacturer often includes deterrent provisions designed to keep later-filing generic manufacturers from entering the market before the delayed entry date to which the first-filer agreed. Two common types of such deterrent provisions are Most Favored Entry clauses ("MFE") and Most Favored Entry Plus clauses ("MFEP").

1. Most Favored Entry Provisions

89. A typical MFE directs that the first-filing generic manufacturer will delay generic entry until some future date, often years in the future. However, the MFE provides that if any other generic manufacturer (*i.e.*, a later filer) is able to enter the market before that date, the first-filing generic manufacturer may immediately enter the market on the same day.

90. The purpose and effect of MFEs is to delay generic entry. This works for brand manufacturers because it drastically disincentivizes the later-filing generic manufacturer from trying to enter the market before the first-filer. Without an MFE, the later-filing generic manufacturer would have a shot at entering the market before the first filer. With an MFE, however, the later-filing generic manufacturer has no incentive to try to beat the first-filer to market: no matter what they do, they would never be the exclusive generic on the market.

91. When a later-filing generic manufacturer obtains a final court decision that the brand manufacturer's patents are invalid or not infringed, the first filer forfeits its period of ANDA exclusivity if it does not enter the market within 75 days of the court decision. 21 U.S.C. §355 (j)(5)(D)(i)(I)(bb). The first filer would forfeit the statutory exclusivity, for example, if it agreed to

delay entry until Year 4 and a later filer got a final court decision of patent invalidity in Year 2. Having agreed not to begin marketing until Year 4, the first filer could not enter the market within 75 days of the later filer's favorable court decision in Year 2. The first filing generic manufacturer would therefore forfeit its period of ANDA exclusivity. Although this is the way the regulatory framework was intended to work, an MFE provision essential thwarts this incentive structure.

92. Specifically, an MFE provision allows the brand manufacturer and the first-filing generic manufacturer, through their joint conduct, to circumvent the statutory incentive for later filers to try to secure an entry date earlier than the one to which the first filer agreed. Absent an MFE, the Hatch-Waxman Amendments would allow the later-filing generic manufacturer to enter in Year 2 and get a substantial period as the only generic product on the market. The first filer would be left watching while the later filer enjoyed generic exclusivity. The prospect of being the only generic product on the market motivates a later filer to incur the substantial costs and burdens of trying to enter the market before the entry date to which the first filer agreed. An MFE eliminates that possibility, deterring later filers from trying to improve on the entry date to which the first-filing generic manufacturer agreed.

93. MFEs thereby result in delayed generic entry in at least two ways: (i) they deter later filers from trying to gain entry before the first filer; and (ii) they eliminate the threat to the first filer's potential period of exclusivity, thus further compensating (beyond the No-AG Agreement) the first filer for delaying its entry into the market. In short, MFEs eliminate later filers' competitive threat to the first filing generic manufacturer, in return for which the first filer agrees to later entry than it otherwise would.

94. The Chairman and CEO of Apotex, Inc., one of the world's largest generic manufacturers, testified to Congress that MFEs "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry." The provisions deter others from entering earlier and cause the first filer to accept a later entry date:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system. If subsequent filers do not have the incentive to take on the

> cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[11]

2. Most Favored Entry-Plus Provisions

95. Brand manufacturers also employ another type of later-filer deterrent to compensate the first-filing generic manufacturer for agreeing to delay entry into the market. A Most Favored Entry-Plus provision ("MFEP") directs that the brand manufacturer will not grant a license to any other generic manufacturer to enter the market (under authority of the generic competitor's ANDA) until a defined period after the first filer enters the market with its generic product. For example, the MFEP could provide that the brand manufacturer will not grant a license to any later filer to enter the market until 180 days after the first-filing generic manufacturer enters.

96. The brand manufacturer might also agree to not grant a license to a later-filing generic manufacturer to enter before the first filer under authority of the brand manufacturer's NDA. Such a restraint is, however, properly classified as a No-AG Agreement rather than an MFEP. An MFEP restricts the brand manufacturer's ability to grant a license to a later filer to enter the market under the authority of the later filer's ANDA.

97. The purpose and effect of an MFEP, like an MFE, is to cause the first-filing generic manufacturer to delay entry into the market and to compensate it for doing so. MFEPs deter later filers from trying to enter the market before the first filer. Absent the MFEP, later-filing generic manufacturers could use their own challenges to the brand manufacturer's patents as leverage to negotiate from the brand manufacturer a license to enter the market before the first filer, thereby

---

[11] Statement of Bernard Sherman, CEO, Apotex, Inc., *available at* http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf at 218 (March 31, 2009).

enjoying a substantial period with the only ANDA product on the market. Those licenses would be very valuable to the later filer where the first filer has forfeited, or might forfeit, its period of ANDA exclusivity.

98. Like an MFE, an MFEP results in delayed generic entry by deterring later filers from trying to gain entry before the first-filing generic manufacturer, thereby compensating the first filer for delaying its entry.

99. When implemented together, MFEPs and MFEs deter later-filing generic manufacturers from trying to enter before the first filer and to compensate the first filer for agreeing to delay entry.

100. Thus, the brand manufacturer and the first-filing generic manufacturer can work together, through No-AG Agreements, MFEs, and MFEPs, to close all pathways to earlier generic entry intended by Congress.

c. The Illegal No-AG Agreement Between Assertio/Santarus and Lupin

i. Assertio and Santarus Marketed Brand Glumetza

101. The active ingredient in Glumetza is metformin hydrochloride. Metformin has been one of the most commonly prescribed oral medications for the treatment of Type 2 diabetes for decades. It improves glycemic control.

102. On June 3, 2005, the FDA approved Assertio's NDA for Glumetza 500 mg and 1,000 mg extended-release tablets, with an indication as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes.

103. Glumetza's extended-release formulation was designed for patients experiencing issues with the efficacy of immediate-release metformin products. Doctors often found it difficult to titrate patients up to the maximum daily recommended dose of 2,000 mg of metformin due to the occurrence of gastrointestinal ("GI") side effects, such as nausea. Some estimates state that up to 50% of metformin-treated patients report GI side effects, and many of those who were unable to tolerate the effects failed to achieve adequate glycemic control.

104. Glumetza's extended-release mechanism works by causing the pill, once ingested into the stomach, to swell with water. The increased size serves the dual purpose of blocking the

drug's exit from the stomach while steadily controlling the drug's release over the course of hours. This ensures the drug's release will occur in the stomach or upper GI tract, rather than the lower GI tract, thereby reducing the risk of GI side effects.

105. Glumetza was therefore uniquely positioned in the market to offer patients with Type 2 diabetes an ability to reach their optimal dose of metformin with fewer GI side effects.

106. In October 2008, Santarus began promoting Glumetza under an exclusive-promotion agreement with Assertio. In August 2011, Santarus and Assertio entered into a new Commercialization Agreement pursuant to which Santarus became the NDA owner and assumed broader commercial, manufacturing, and regulatory responsibilities, including exclusive rights to manufacture and commercialize Glumetza in the United States.

107. Under this agreement, Santarus assumed sole decision-making authority on pricing, contracting, and promotion for Glumetza. Santarus also had the exclusive right to commercialize authorized-generic versions of the drug.

108. Under the Commercialization Agreement, Santarus agreed to pay Assertio a gradually increasing royalty rate (reaching a ceiling of 34.5% by 2015) on net sales of Glumetza before generic Glumetza entry. In the event a generic version of Glumetza entered the market, the parties agreed to equally share proceeds based on a gross margin split.

109. In addition, the Commercialization Agreement provided that Assertio would manage any patent-infringement lawsuits relating to patents covering Glumetza, subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. The parties also agreed to split the costs of any patent lawsuit, with Santarus responsible for 70%, and Assertio responsible for 30%.

ii. Assertio's Narrow Glumetza Patents Could Not Prevent Generic Competition

110. The patent protection for Glumetza was extremely narrow. The patents neither purported to claim metformin, nor to claim a pharmaceutical formulation (*e.g.*, tablet, capsule, injection, etc.) of metformin alone or the method of using metformin alone to treat diabetes. The drug substance had long since been used in pharmaceutical formulations to treat Type 2 diabetes.

Instead, all relevant patents relate to oral dosage forms that provide extended, controlled release of a drug such as metformin.

111. Furthermore, the patents on Glumetza did not purport to broadly claim controlled- or extended-release technology, which was developed in the 1970's and has since been used in a variety of applications. Controlled- or extended-release technology typically involves a polymeric formulation, which is a large molecule composed of repeating structural units, using either "reservoir" or "matrix" systems.

112. In a reservoir system, a core containing the active drug is coated with an acrylic polymer composition to help achieve extended release.

113. In a matrix system, the drug is dissolved or dispersed throughout the polymer and then formulated into a pill. After the patient swallows the pill, gastric fluids cause the matrix to swell to a size large enough to maintain the dosage form in the stomach during the fed mode (*i.e.*, after a meal). This water-swollen polymeric matrix controls the rate at which the drug is released from the dosage form.

114. The patents on Glumetza focus on a narrow range of formulations and methods that require a matrix controlled-release system. Assertio's patents did not even purport to invent the matrix system for metformin. Indeed, there were many prior-art options for extended-release delivery vehicles targeting the stomach, including: (i) a solid matrix formed of a substance that absorbs gastric fluid and swells as it absorbs fluid to extend gastric retention of the delivery vehicle, such as disclosed in U.S. Patent No. 5,007,790, "Sustained-Release Oral Drug Dosage Form," issued April 16, 1991; (ii) a matrix that limits the rate at which the surrounding gastric fluid diffuses through the matrix, reaches the drug, dissolves the drug, and diffuses out again; and (iii) a matrix that slowly erodes, continuously exposing fresh drug to the surrounding fluid, such as disclosed in U.S. Patent No. 4,915,952, "Composition Comprising Drug, HPC, HPMC, and PEO," issued April 10, 1990.

115. The patents on Glumetza narrowly pertain to a particular type of water-swollen polymeric matrix that is responsible for controlled drug delivery. Glumetza's patents require, *inter alia*, particular drug-release rates, drug-to-polymer ratios, dosage forms of particular sizes and

shapes and duration, the use of specific polymers in sufficient quantities to perform the required functions, and specific manufacturing processes. One or more of these claim limitations define the purported inventions.

116. Assertio, as the party asserting infringement, would have the burden of proving that the generic manufacturer's product falls within every limitation of an asserted patent's claim; a generic manufacturer would prevail if its product fell outside even just one limitation of each asserted claim.

117. Generic manufacturers could avoid infringing, *i.e.*, they could "design around," the patents by forgoing the "matrix system" altogether. They could instead use the entirely different "reservoir system," designed to provide controlled release of the drug without, *e.g.*, "substantially retain[ing] its size and shape without deterioration until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached or remaining substantially intact until substantially all of the drug is released." [12] A generic version of Glumetza using such a reservoir system would necessarily fall outside all the relevant patents' claims. In other words, a generic version of Glumetza that used the reservoir system instead of the matrix system would not infringe the Glumetza patents.

118. As noted *supra*, the prior art already taught how to incorporate a reservoir system, defined as using a core containing the active drug that is coated with an acrylic polymer composition to help achieve extended release. For example, U.S. Patent No. 4,954,350, "Pharmaceutical Formulations Containing Acrivastine," issued September 4, 1990, (the "PFCA Patent") discloses controlled-release pharmaceutical formulations for oral administration of acrivastine (an anti-histamine) utilizing a core containing the drug coated with acrylic polymers. The PFCA Patent specifically identifies a neutral polymer based on ethyl acrylate and methyl methacrylate, Eudragit E30D ("Eudragit"), as one of the commercially available acrylic polymers that can be used as a coating. The PFCA Patent also discloses other prior art references of delayed-

[12] *See Depomed, Inc. v. Lupin Pharms., Inc.*, No. 09-cv-5587, ECF No. 131-5 (N.D. Cal. Jan. 6, 2012).

release formulations containing a core of other active ingredients coated with a polyacrylate insoluble that is dispersible in water, such as Eudragit.

119. In short, a pivotal difference between the matrix and reservoir systems is the rate-controlling mechanism. In a matrix system, the mechanism controlling the rate of drug release is the polymeric matrix. In a reservoir system, by contrast, the rate-controlling mechanism is a polymeric membrane encasing the drug core.

120. Although the FDA requires proposed generic products to satisfy certain "sameness" requirements, having an identical controlled-release mechanism is not among them. As long as the generic manufacturer can assure the FDA that its product releases the drug at a similar rate and to a similar extent as the branded reference drug (thereby establishing bioequivalence), the FDA will not block the generic's approval on the ground that it uses a different controlled-release mechanism, such as a reservoir system.

121. Lupin's use of a reservoir system avoided each of Assertio's patents listed in the Orange Book as identified *supra*. Lupin's ANDA generic product did not infringe Assertio's Glumetza patents.

122. The '475 and '280 Patents are based on the same initial patent application and therefore disclose the same invention. Both patents require a controlled-release dosage form in which a "drug is dispersed in a polymeric matrix that is water-swellable." As the patents explain, "the swelling of the polymeric matrix ... achieves two objectives—(i) the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode, and (ii) it ... provide[s] multihour, controlled delivery of the drug into the stomach." In this way, "[t]he rate limiting factor in the release of drug is therefore controlled diffusion of the drug from the matrix." Accordingly, the basic and purportedly novel properties of the '475 and '280 Patents are the polymeric matrix's ability to control the rate of drug release from the dosage form by swelling to promote retention in the stomach and having an erosion rate that is substantially slower than its swelling rate.

123. A reservoir system can achieve the desired controlled release without relying on a polymeric matrix having the properties required by the '475 and '280 Patents. A reservoir system wraps the drug core with a separate polymer coat that contains distinct chemical properties and

represents an insoluble, physical barrier. The rate-limiting factor in the release of the drug is controlled by the diffusion not from the matrix, as would be required under the'475 and '280 Patents, but from the polymer coat.

124. Due to their narrowness, neither the '475 Patent nor the'280 Patent could prevent a generic Glumetza product from launching before those patents expired in September 2016. Furthermore, since Assertio listed these patents in the Orange Book for only Glumetza's 500 mg strength, they clearly could not block approval of a generic Glumetza 1,000 mg ANDA. In any event, the patents' narrow scope could not prevent a generic manufacturer from receiving FDA approval and launching generic versions of Glumetza 500 and 1,000 mg, especially ones using a reservoir system.

125. Use of a prior-art reservoir system also allowed a generic manufacturer to design around the remaining, later-expiring Glumetza patents.

126. The '962 Patent merely purports to offer an improvement over the '475 and '280 Patents and covers "tablet shapes to enhance gastric retention of swellable controlled-release oral dosage forms." In terms of avoiding infringement, the "consisting essentially of" claims of the '962 Patent can be avoided either by a dosage form having a shape that differs from that claimed or by using a delivery vehicle that materially differs from that of a solid monolithic matrix. A generic manufacturer would avoid infringing the '962 Patent simply by virtue of using a non-swellable polymer coat, rather than a matrix, which materially affects the dosage form to control the drug's release.

127. The '340 Patent, which is also narrow, purportedly covers optimal material to be used in the matrix system for it to control the drug's release. Again, a generic manufacturer would therefore easily avoid infringing the '340 Patent by using the host of other available materials to carry the drug rather than the specific claimed matrix of poly(ethylene oxide) and hydroxypropyl methylcellulose, to control the drug's release.

128. Both the '987 and '692 Patents disclose a dosage form requiring a controlled-release coating that must be prepared by "curing the coated oral dosage form at a temperature of at least 55° C" and must consist of a neutral ester copolymer, a polyethylene glycol, one or more hydrophilic

agents, and a pharmaceutically acceptable excipient. A generic manufacturer would easily design around those patents' claims by applying a different prior art coating to control the drug's release.

129. The '987 and '692 Patents, having been listed for only the 1,000 mg Glumetza product, clearly could not block a generic Glumetza 500 mg ANDA. Moreover, the patents' narrow scope could not prevent a generic manufacturer from receiving FDA approval and marketing generic versions of either 500 mg or 1,000 mg Glumetza.

iii. Assertio's Sham Patent Lawsuits

1. Against Lupin

130. The active ingredient in Glumetza, metformin, was not patent protected, and other acceptable delivery vehicles existed in the prior art. Lupin recognized the opportunity to develop and market a competing generic Glumetza product.

131. On or about July 27, 2009, Lupin filed ANDA No. 91664 seeking FDA approval to manufacture and sell generic versions of 500 mg and 1,000 mg Glumetza. Lupin's ANDA contained a Paragraph IV certification to all applicable Glumetza patents. At the time, Assertio had listed in the Orange Book only the '475, '280, '962, and '340 Patents for Glumetza.

132. On or about November 6, 2009, Lupin notified Assertio that Lupin had filed ANDA No. 91664, detailing why the relevant patents were both invalid and not infringed by Lupin's ANDA product.

133. On November 25, 2009, Assertio sued Lupin in the U.S. District Court for the Northern District of California, claiming infringement of the '475, '280, '962, and '340 Patents.[13] Assertio's timely lawsuit triggered Hatch-Waxman's automatic 30-month stay against Lupin's entry into the market, measured from the date Assertio received Lupin's November 6, 2009 Paragraph IV notice letter.

134. Assertio filed the patent infringement lawsuit against Lupin without regard to the lawsuit's merits; it was a sham. Assertio knew that there was an overwhelming likelihood that it

[13] *Depomed, Inc. v. Lupin Pharms., Inc.*, No. 09-cv-5587 (N.D. Cal.). Assertio also filed a second patent infringement lawsuit against Lupin, *Depomed, Inc. v. Lupin Pharms.*, No. 09-cv-3406 (D. Md.), which was voluntarily dismissed shortly after filing.

would lose the patent litigation. Assertio's true purpose in bringing the lawsuit was to ensure that it received the automatic 30-month stay of any generic competition. By filing the case, Assertio effectively excluded Lupin from obtaining FDA approval and coming to market until May 6, 2012.

135. On January 29, 2010, Lupin filed its answer to Assertio's complaint, asserting that the manufacture, use, offer for sale, sale, or importation of its ANDA product would not infringe any valid and enforceable claim of the relevant patents.

136. As the litigation proceeded, Assertio dropped its claim of infringement relating to the '340 Patent.

137. On August 26, 2011, Lupin provided supplemental interrogatory responses disclosing that its ANDA product does not and cannot infringe Assertio's patents because it uses a reservoir system rather than a polymeric matrix system to extend the drug's release.[14]

138. Relying on key differences between its reservoir-system product and the matrix system products claimed under the Glumetza patents, Lupin established that its product does not meet the patents' requirements that: (i) the product remain "substantially intact" until all of the drug is released; (ii) the product's drug core "substantially retain its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles" until "at least about 80% of the drug has been released after eight hours of immersion in gastric fluid"; and (iii) "the drug is released at a rate controlled by the rate of diffusion" out of the polymeric matrix.

139. Lupin further explained that its reservoir delivery system used a coating that included Eudragit to control the drug's release, rather than being controlled by the polymeric matrix core as required by the Glumetza patents. As alleged *supra*, controlled-release delivery vehicles based on a coating containing acrylic polymers, such as Eudragit, were well known in the prior art.

140. On January 27, 2012, the FDA tentatively approved Lupin's ANDA, meaning that Lupin's ANDA product could receive final approval for marketing as an AB-rated generic as early as the expiration of the 30-month stay in May 2012. After final approval, Lupin would be eligible

---

[14] *See Depomed, Inc. v. Lupin Pharms., Inc.*, No. 09-cv-5587, ECF No. 131-5 (N.D. Cal. Jan. 6, 2012).

to launch its generic Glumetza at risk—before a final, non-appealable judgment in the patent case. The tentative approval thus signaled to Assertio and Santarus a significant risk that Lupin was just months away from launching a non-infringing AB-rated generic Glumetza. Moreover, even if Lupin waited until its victory in the patent infringement litigation, Lupin would likely enter the market in late 2012 or early 2013 because the patent case was scheduled for trial in October 2012.

141. Lupin's marketing a generic Glumetza product would have devastated Assertio's and Santarus' bottom line. As of January 2012, Glumetza represented over 50% of Santarus' sales.

142. Lupin posed a particularly significant threat of launching at-risk. In September 2011, Lupin had launched at-risk a generic version of Fortamet. Like Glumetza, Fortamet consisted of 500 mg and 1,000 mg extended-release tablets of metformin hydrochloride. Moreover, Lupin had launched generic Fortamet shortly after expiration of that 30-month stay, exactly the same juncture that Lupin was then approaching in the Glumetza litigation.

143. Santarus and Assertio also knew that, if the litigation proceeded, the overwhelming likelihood was that the Lupin product would be found not to infringe the Glumetza patents. As alleged *supra*, Lupin's generic used a reservoir system, which is not covered by the relevant patents. Lupin therefore had an extraordinarily small likelihood that any at-risk launch would later subject it to liability for patent damages.

144. In short, Assertio and Santarus believed, correctly, that Lupin intended to begin marketing generic Glumetza in May 2012 unless the parties settled the patent litigation.

2. Against Sun

145. Sun was the second would-be generic manufacturer, after Lupin, that filed an ANDA seeking to market generic versions of 500 mg and 1,000 mg Glumetza tablets before the expiration of Assertio's (then named Depomed) Orange Book-listed patents.

146. On or about May 6, 2011, Sun notified Assertio that Sun had filed ANDA No. 202917, which notice contained a Paragraph IV certification, detailing why its generic Glumetza product did not infringe a valid claim of the relevant Orange Book patents.

147. On June 20, 2011, Assertio sued Sun for patent infringement in the U.S. District Court for the District of New Jersey, asserting the '962, '340, '280, '475, and '987 Patents that were

listed in the Orange Book.[15] Valeant International Bermuda ("VIB") joined the suit as a co-plaintiff because it owned the '987 Patent and exclusively licensed it to Assertio. Assertio and VIB sued Sun within 45 days of receiving Sun's Paragraph IV certification, so the automatic 30-month stay prohibiting Sun's entry into the market began to run on or about May 6, 2011, and would expire on or about November 6, 2013.

148. Assertio also sued Sun for infringement of U.S. Patent No. 7,736,667 ("the '667 Patent"), which is not listed in the Orange Book. The '667 Patent discloses a dual-matrix, controlled release oral dosage form. The first matrix—the "core"—is comprised of a water-swellable polymeric material "in which drug is dispersed." The second matrix—the "shell"—forms a "casing that surrounds and fully encases the core." This shell is comprised of a water-swellable polymeric material "that swells upon imbibition of water (and hence gastric fluid) to a size large enough to promote retention in the stomach during the fed mode[.]" A drug employing a reservoir system does not, by definition, use a dual-matrix system with a core and shell that each swell upon imbibition of water. Thus, the '667 Patent, like the other Glumetza patents, did not pose a bar to a generic that uses a reservoir system.

149. Like Lupin before it, Sun denied that the relevant patents covered its ANDA product, asserting that its proposed generic tablet controlled the release of metformin using a reservoir system in which a drug core is covered by a polymeric membrane, rather than a matrix system claimed under the patents.

150. On January 25, 2013, Assertio/Santarus and VIB entered into an agreement that terminated Sun's challenge to the Glumetza patents. During the negotiations leading to that agreement, Sun was aware that Assertio/Santarus had agreed to an MFE and MFEP with Lupin, which significantly diminished Sun's incentive to continue its challenge. Consequently, Sun agreed that it would not begin selling a generic version of Glumetza until 180 days after Lupin's delayed entry date.

[15] *Depomed, Inc. v. Sun Pharma Global FZE, et al.*, No. 11-cv-3553 (D.N.J.).

151. It is unknown to Plaintiff at the present time whether Assertio/Santarus made any payment to Sun (or agreed to other terms with Sun) to help ensure that it would not enter the market before August 2016.

3. Against Watson

152. Watson was the third would-be generic manufacturer, after Lupin and Sun, that filed an ANDA seeking to market generic versions of 500 mg and 1,000 mg Glumetza tablets before the expiration of Assertio's (then named Depomed) Orange Book-listed patents.

153. Initially, Watson filed an ANDA for a 1,000 mg product only. On or about March 7, 2012, Watson notified Assertio and VIB that Watson had filed ANDA 203755, which notice contained a Paragraph IV certification, detailing why its generic 1,000 mg Glumetza product would not infringe a valid claim of the relevant Orange Book patents.

154. On April 18, 2012, Assertio and VIB filed a lawsuit in the U.S. District Court for the District of Delaware against for infringement of the patents listed in the Orange Book for the 1,000 mg Glumetza product at the time the lawsuit was filed (the '962 and '987 Patents).[16] Assertio and VIB sued Watson within 45 days of receiving the Paragraph IV certification, and the automatic 30-month stay prohibiting Watson's entry into the market would expire on or about September 7, 2014.

155. In February 2013, Assertio and VIB amended their complaint to add infringement of a newly listed Orange Book patent (the '692 Patent), as well as two non-Orange Book listed patents (the '667 Patent and U.S. Patent No. 8,329,215 ("the '215 Patent")).

156. The '215 Patent, like the '667 Patent, discloses a dual-matrix system where a dosage form employs a core and shell that each swell upon imbibition of water. As explained above, a product using a reservoir system does not have such properties and so falls outside the scope of the '215 Patent's claims.

157. On February 28, 2013, Assertio filed a new complaint in the U.S. District Court for the District of Delaware against Watson for infringement of the '962, '340, '280, '475 Patents.[17] Assertio filed the lawsuit in response to Watson's providing Assertio a Paragraph IV notice letter,

---

[16] *Depomed, Inc. v. Watson Labs., Inc.*, No. 12-cv-492 (D. Del.).
[17] *Depomed, Inc. v. Watson Labs., Inc.*, No. 13-cv-342 (D. Del.).

dated January 18, 2013, stating that Watson had amended its ANDA 203755 with the intent to market a generic version of 500 mg Glumetza tablets, in addition to the previously noticed 1,000 mg tablets, before the relevant Orange Book-listed patents expired. The 30-month stay automatically precluding Watson's generic 500 mg Glumetza product would not expire until on or about July 18, 2015.

158. On November 8, 2013, Assertio/Santarus and VIB entered into an agreement that terminated Watson's challenge to the Glumetza patents. During the negotiations leading to that agreement, Watson was aware that Assertio/Santarus had agreed to an MFE and MFEP with Lupin, which significantly diminished Watson's incentive to continue its challenge. Consequently, Watson agreed that it would not begin selling a generic version of Glumetza until at least 180 days after Lupin's delayed entry date.

159. It is unknown to Plaintiff at the present time whether Assertio/Santarus made any payment to Watson to help ensure that it would not enter the market before August 2016.

iv. Assertio and Santarus Paid Off Lupin to Keep Generic Competition Off the Market for Years

160. To avoid the substantial probability that Lupin would launch a non-infringing generic Glumetza product either at risk or after prevailing in Assertio's sham patent infringement litigation, Assertio and Santarus decided to extend the period of Glumetza's supracompetitive profits by paying Lupin, in at least the form of the No-AG Agreement, to withdraw its patent challenges and delay introducing generic Glumetza.

161. On February 22, 2012, shortly after Lupin's January 2012 tentative approval and shortly before the 30-month stay would expire in May 2012—Assertio/Santarus and Lupin entered into an agreement whereby Lupin agreed to end its challenge to the Glumetza patents and substantially delay entering the market, in exchange for a No-AG Agreement.

162. Under the agreement, Lupin agreed to refrain from entering the market with a generic Glumetza until February 1, 2016 (subject to the MFE and MFEP clauses discussed herein). In exchange for Lupin's agreement to delay its entry for nearly four years, Assertio and Santarus agreed not to market authorized generic 500 mg and 1,000 mg Glumetza products, and not to

license any other manufacturer to market such a product under Assertio's NDA, for at least 180 days after Lupin's entry into the market.

163. Upon information and belief, the term of the No-AG Agreement secretly extended an entire year following Lupin's launch, not just 180 days. In fact, Valeant refrained from entering the market with its authorized generic version of Glumetza until February 2017, a full year after Lupin's generic entered the market.

164. The purpose and effect of the No-AG Agreement was to induce Lupin to abandon its patent challenge and agree not to compete with a generic version of Glumetza until February 2016. Assertio and Santarus would not have agreed to the No-AG Agreement without securing, in exchange, Lupin's agreement not to market a generic version of Glumetza until February 2016. Likewise, Lupin would not have agreed to a delayed February 2016 entry without securing, in exchange, Assertio's and Santarus' commitment to the No-AG Agreement.

165. Absent the No-AG Agreement, Santarus had the incentive and ability to market an authorized generic version of Glumetza immediately upon (if not before) Lupin's entry. For example, Santarus launched an authorized generic simultaneously with the first filer's launch of generic Zegerid. A rational, profit-maximizing entity in Santarus' position would not forgo an opportunity to gain additional sales by marketing an authorized generic. Indeed, Santarus ensured that its commercialization agreement with Assertio gave Santarus the right to launch a Glumetza authorized generic.

166. By giving up the unqualified right to earn profits from marketing its own authorized generic, Santarus enabled Lupin to make approximately twice the unit sales, at a much higher price, all at the expense of Plaintiff and Class members. The No-AG Agreement thus served as substantial compensation for Lupin's agreement to delay its entry, and Lupin could not have obtained this payment or its equivalent even if Lupin had won the patent litigation against Assertio.

167. The No-AG Agreement's value to Lupin is readily calculable using the known economics of the pharmaceutical industry. Assuming, conservatively, that the term of the No-AG Agreement extended only six months, and not a year as suspected, the valuation from Lupin's perspective is a matter of estimating the additional sales it expected to make during its first six

months of marketing in 2016 compared to the sales it expected to make in the first six months of entry in 2012 when, without the benefit of the No-AG Agreement, it would have faced competition from Santarus' authorized generic.

168. For 2012, annual sales of Glumetza were approximately $150 million. Six months (approximately 180 days) of brand Glumetza sales would generate revenue to Assertio/Santarus of approximately $75 million (0.5 years * $150 million).

169. Lupin expected generics to take 80% of Glumetza unit sales during those six months. Lupin therefore expected generics to capture approximately $60 million worth of brand units during those six months ($75 million * 80%).

170. In the absence of the No-AG Agreement, Lupin expected two generics (its own, and Santarus' authorized generic) to be in the market during those 180 days. Studies by the FDA and others show that, with two generics in the market, the average generic price is driven down to a 48% discount off the brand price. Lupin expected that the two generics would sell the $60 million worth of brand units during those six months for a total of $31.2 million ($60 million * 52%).

171. Lupin expected, however, that it would not receive all of those revenues. Instead, the unit sales of the generic during the six months would be split (roughly evenly) between Lupin and the Santarus authorized generic. In fact, the authorized generic often captures more than half of the unit sales due to a "first-mover" advantage and other marketing advantages. Thus, without the No-AG Agreement, Lupin expected that its revenues during the six months would be at most $15.6 million ($31.2 million * 50%).

172. With the anticompetitive No-AG Agreement, Lupin knew that it would fare far better financially. First, Lupin would make 100% (not 50%) of the generic sales in the first six months.

173. Second, Lupin would make those sales at a far higher price. Lupin knew that the absence of a competing generic would enable it to sell its generic Glumetza at only a 10% discount off the price of the brand, rather than a 48% (or greater) discount.

174. Third, Lupin expected that the brand sales revenue, driven by both increased unit sales and increased prices, would be far higher in 2016 than it would be in 2012. Santarus had just recently assumed full responsibility for commercializing Glumetza. Its sales were quickly rising,

having doubled in the first quarter of 2012 compared to the first quarter of 2011. Santarus had just hired 30% more sales representatives and rolled out a new promotional program, prompting analysts to predict very significant sales growth. Consequently, Lupin expected annual brand sales as of 2016 to be at least $200 million.

175. Thus, with the No-AG Agreement in place, Lupin expected the value of its generic Glumetza sales during the six-month period in 2016 to be at least $72 million ($200 [annual brand sales] * 0.5 years * 80% [percentage of sales taken by generic] * .9 [assuming a 10% price discount]).

176. The No-AG Agreement's value to Lupin was, at a minimum, the difference between the value of six months of marketing in 2012 with an authorized generic on the market, and six months of marketing in 2016 without an authorized generic on the market. That difference is $56.4 million ($72 – $15.6). The No-AG Agreement's value to Lupin was far more than it could have made even if it had won the patent litigation.

177. In fact, the No-AG Agreement's value to Lupin far exceeded $56.4 million, even setting aside the potential that the No-AG Agreement's term was for a year rather than a half-year. Lupin was well aware of this fact. Lupin knew and intended that its agreement to delay entry until 2016 would encourage Assertio and Santarus to exploit the market power that Lupin's agreement had secured for them. As set forth further in detail *infra*, Assertio and Santarus got that bought-and-paid-for monopoly into the hands of another brand manufacturer that was able to fully exploit it. That manufacturer—Valeant—used the generic-free time period to raise the price of branded Glumetza by nearly 800%, causing the dollar sales to rise to more than $1.2 billion annually by 2016.

178. Thus, the No-AG Agreement resulted in Lupin's making sales in the six-month period in 2016 of some $295 million. This is $280 million more than Lupin would have made by marketing the product for six months in 2012 with an authorized generic on the market. And this assumes that the No-AG Agreement's term was only six months, and not a full year.

179. The No-AG Agreement resulted in Assertio and Santarus forgoing between $15.6 million and $31.2 million in sales of an authorized generic in 2012 (depending on whether the No-

AG Agreement term was six months or a year). But the No-AG Agreement caused Lupin to delay entry into the market by nearly four years. That delay was worth hundreds of millions, if not billions, to Assertio and Santarus and their successors. And that is how much Glumetza purchasers have been overcharged.

180. Assertio's and Santarus' No-AG Agreement to Lupin impaired competition in at least three ways. First, it allocated 100% of the Glumetza market to Assertio and Santarus for the period before generic competition. Second, it allocated 100% of the generic segment of the market to Lupin for at least 180 days (if not a full year). Third, it substantially delayed entry by all generic manufacturers.

181. Had Assertio and Santarus not paid Lupin to drop its patent challenge and delay generic entry, Lupin would have marketed its less expensive generic Glumetza either: (a) "at-risk" (*i.e.*, while the patent litigation was pending) upon the expiration of the 30-month stay; (b) upon winning the patent litigation; or (c) earlier than February 1, 2016, on a date to be determined by a jury, pursuant to a lawful settlement agreement without a large unjustified payment from Assertio and Santarus to Lupin. Absent the No-AG Agreement, immediately upon Lupin's entry into the market (or before), Assertio and Santarus, as rational economic actors seeking to recoup lost branded sales, would have sold authorized generic Glumetza in competition with Lupin, driving prices down even further.

182. Defendants have no procompetitive explanation or justification for the No-AG Agreement. The large, unjustified payment had no rational connection to, and far exceeded, any approximation of the costs of continuing the patent litigation. Typical litigation costs for patent cases of this nature rarely exceed a few million dollars. Assertio and Santarus' future expected litigation costs at the time it unlawfully paid Lupin, after two years of patent litigation, were much less than that.

183. The No-AG Agreement was anticompetitive and unlawful regardless of whether it constitutes a reverse payment.

v. The Assertio/Santarus and Lupin Deal Kept Other Generics Off the Market

184. The No-AG Agreement significantly delayed competition from Lupin and deprived consumers and third party payors of Glumetza dramatically lower prices for branded and generic Glumetza. But other potential sources of competition remained: other generic manufacturers. So Assertio, Santarus, and Lupin included other anticompetitive provisions in their settlement to neutralize those potential threats.

185. As the first filer, Lupin was eligible to receive the 180-day period of ANDA exclusivity. As detailed *supra*, however, Congress left open pathways for later-filer generic manufacturers to try to come to market before the entry date agreed between the first filer and the patent holder, despite the 180-days of generic ANDA exclusivity. Those later filers can enter the market with their ANDA-approved products even where the FDA has awarded 180-day generic ANDA exclusivity to the first-filing generic manufacturer. (The No-AG Agreement precluded Assertio/Santarus from allowing a later filer to enter before Lupin pursuant to a license under Assertio's NDA).

186. As applicable here, a later filer could get a final court decision that its generic Glumetza product did not infringe any of Assertio's valid patents. In that event, Lupin would forfeit its generic ANDA exclusivity if it failed to enter the market within 75 days of the court decision. 21 U.S.C. §355 (j)(5)(D)(i)(I)(bb). Having agreed to delay entry until February 1, 2016, Lupin would fail to enter within 75 days, and therefore would forfeit, if a later filer got the final court decision before November 18, 2015. That forfeiture would allow the later filer to enter before Lupin. After Lupin forfeited its generic ANDA exclusivity, additional later filers could enter before Lupin. They could enter before Lupin by winning their patent litigations or using the leverage of their patent challenges to get a license from Assertio/Santarus.

187. Two circumstances created an overwhelming likelihood that Congress's incentives for a later filer would work, resulting in a final court decision that deprived Lupin of generic ANDA exclusivity. First, as detailed *supra*, Assertio's patents on Glumetza were extremely narrow and could easily be designed around (*i.e.*, the generic formulations would not infringe them). Lupin could and did design around them simply by using a reservoir system rather than a matrix system. Assertio/Santarus and Lupin knew that other generic manufacturers could do the same thing.

188. Second, Lupin agreed to a delay in generic entry of nearly four years. As alleged *supra*, in February 2012 when Assertio/Santarus and Lupin agreed to their No-AG Agreement, later filer Sun was well into its patent litigation with Assertio/Santarus. That litigation could reasonably be expected to be completed, through a final court decision, by no later than February 2015. Sun could therefore have expected a substantial reward, in the form of a year or more of exclusive or semi-exclusive sales in the generic sector, for reaching the market before Lupin.

189. Assertio/Santarus and Lupin avoided that probability by including an MFE and an MFEP in their agreement. The MFE provided that, if any other generic manufacturer succeeded in entering the market with generic Glumetza before Lupin's scheduled February 1, 2016 date, Lupin's entry would be moved up accordingly. The MFEP provided that Assertio/Santarus would not grant a license to any other manufacturer to enter the market with generic Glumetza until a date that was at least 180 days after Lupin entered with its generic Glumetza product.

190. Without the MFE and MFEP, Lupin faced a high likelihood that it would be stuck on the sidelines while later filers entered the market a year or more in advance and reaped the corresponding gains of being the first ANDA entrants.

191. Congress intentionally left open those pathways for later filers to enter first and enjoy periods of exclusivity or semi-exclusivity. Those pathways created incentives for later filers to enter the market before a delayed entry date to which a first filer agreed. As detailed *supra*, the purpose and effect of MFEs and MFEPs is to undermine those incentives. The MFE and MFEP agreed between Assertio/Santarus and Lupin ensured that later filers could not in fact benefit from the two pathways (litigation victory or better license) that Congress intentionally left open for later filers to improve on the entry date to which Lupin had agreed.

192. In short, Assertio/Santarus and Lupin's purpose in agreeing to the MFE and MFEP was to: (1) deter later filers from trying to enter the market before Lupin's delayed February 2016 entry date; and (2) eliminate the threat that later filers would use the statutory incentives to eliminate Lupin's generic ANDA exclusivity, thus further compensating Lupin (beyond the No-AG Agreement) for agreeing to that four-year delay. In short, the MFE and MFEP deterred later filers from trying to enter the market before Lupin, in return for which Lupin agreed to later entry.

193. Absent the No-AG Agreement, MFE, and MFEP to which Assertio/Santarus and Lupin agreed, Sun and Watson would have entered the market much sooner than they did, on dates to be determined by the jury. The delay in generic entry protected hundreds of millions, if not billions in branded Glumetza sales, all at the expense of Plaintiff and other members of the Classes.

vi. Defendants Reaped the Benefits of Their Manufactured Monopoly

194. The Glumetza monopoly that Assertio/Santarus and Lupin created and maintained was an extremely valuable asset. They wasted no time in getting it into the hands of a commercial entity that mercilessly and ruthlessly exploited it, with devastating consequences for Glumetza purchasers.

195. As of February 2012, Assertio/Santarus was selling branded Glumetza at more than five times the price that a fully competitive generic sector would have delivered. Glumetza purchasers could get relief from that high price through three potential means: (i) generic entry by Lupin; (ii) entry by an Assertio/Santarus authorized generic; or (iii) entry by later filers. The No-AG Agreement between Assertio/Santarus and Lupin extended the Glumetza monopoly by four years rather than ending it and compounded the injury by ensuring the absence of an authorized generic (whether sold by Santarus or a licensee) once Lupin belatedly entered the market. Assertio/Santarus and Lupin also agreed to the MFE and MFEP to ensure that no later filers would upend their anticompetitive scheme by entering the market with an ANDA generic before Lupin's delayed entry date. The No-AG Agreement, MFE, and MFEP closed off every available avenue of generic competition. Rather than ending the Glumetza monopoly, those clauses ensured that it would extend for at least another four years.

196. That guaranteed four-year monopoly was enormously valuable, and Assertio/Santarus immediately cashed in on it by selling it to those who could more effectively exploit it. Through the anticompetitive conduct alleged herein, Assertio and Santarus had pushed Lupin's entry out to February 2016 and Sun's and Watson's out to, at the earliest, August 2016.

197. Additionally, on November 7, 2013, Defendant Salix announced that it had reached an agreement to acquire Santarus. Salix withheld final agreement to that acquisition until it was assured that Assertio and Santarus had reached a deal with Watson to delay marketing its generic

Glumetza until August 2016. Salix's CEO reported to stock analysts that Salix was "comfortable" with the acquisition because Glumetza would not be "lost to generics" until 2016.

198. When Salix was negotiating for the acquisition, Glumetza accounted for just under half of Santarus' annual sales. Under the acquisition agreement, Salix agreed to pay $2.6 billion for Santarus. That purchase price represented a 37% premium to Santarus' share price before the acquisition was announced.

199. Then Salix too cashed in on the Glumetza-monopoly sweepstakes. Just 13 months after acquiring Glumetza, in February 2015 Salix announced that it was being acquired by Valeant.

200. When Valeant acquired Salix in April 2015, Glumetza accounted for over 25% of Salix's sales. Valeant paid $14.5 billion for the Glumetza monopoly and the other Salix assets.

201. The Glumetza monopoly was the perfect asset for Valeant to acquire. Valeant did not believe in developing new drugs for the betterment of people. It believed in buying existing drug product monopolies and exploiting them to the fullest extent. Valeant is an example of an extreme recidivist in this area. During the relevant time, Valeant's annual Research and Development budget was less than 3% of its revenues, about a fifth of the pharmaceutical industry average. The motto of Valeant's CEO was "Don't bet on science—bet on management." He called investing in pharmaceutical research "a losing proposition."

202. Valeant's board of directors implemented its "forget science, exploit existing monopolies" strategy by operating the company like a hedge fund and paying its executives as if they were hedge-fund managers. Valeant paid relatively little cash compensation to top executives, but granted them massive stock options that vested only if the company reached aggressive revenue goals.

203. Valeant reached those goals by acquiring companies like Salix that had existing drug monopolies. Valeant would then slash the workforce, especially the scientists, and impose enormous price increases on the already existing monopolized drugs. *Forbes* described Valeant's strategy as one that "emphasized boosting drug prices, gutting research and development budgets,

[and] firing employees."[18] "[S]cientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary."[19] Some pharmaceutical manufacturers may refrain from fully exploiting drug monopolies, based on their longer-term outlooks or concerns about public scrutiny. Valeant lacked any such qualms.

204. A former executive later acknowledged that Valeant's culture was "We're the bad boys, we're successful, we can do whatever we want."[20] The CEO admitted publicly that "[a]ll I care about is our shareholders" and that, "from [an investor's] standpoint [raising prices] is not a bad thing."[21] Industry observers opined that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned."[22]

205. Glumetza purchasers were among the "every other consideration" that Valeant scorned. Immediately after acquiring the Glumetza monopoly, Valeant applied its corporate strategy of fully exploiting existing monopolies. Valeant bought the Glumetza monopoly from Salix in April 2015. By the end of July 2015, Valeant had raised the price of a 30-day supply by over 750%, from $350 to more than $3,000.

206. Glumetza's massive price increase was made possible only by the unlawful agreements that delayed Lupin's generic entry to 2016. Valeant's price hike worked solely because a generic had not already entered the market and taken the unit sales at dramatically lower prices. Absent the No-AG Agreement, Lupin would have begun marketing generic Glumetza long before Valeant's acquisition of Salix, as early as May 2012. Lupin's earlier entry thus would have deprived Valeant and anyone else of the opportunity to exploit the Glumetza monopoly.

207. Valeant's exploitation of the Glumetza monopoly and other drug-product monopolies drew the attention of the U.S. Congress, which held a number of hearings into Valeant's strategy of forsaking science in favor of price increases on existing drug-product monopolies. The hearings established that Valeant set drug prices to reach pre-determined revenue

---

[18] Vardi & Gara, *supra*.
[19] *Id.*
[20] McLean, *supra*.
[21] *Id.*
[22] *Id.*

goals, and "sought to exploit [its] temporary monopol[ies] by increasing prices dramatically to extremely high levels very quickly."[23]

208. In a February 4, 2016 hearing, Representative Cummings specifically highlighted Valeant's exploitation of the Glumetza monopoly, noting that Valeant raised its price "by a whopping 800 percent over a mere six-week period."[24] He noted that Valeant's "basic strategy has been to buy drugs that are already on the market and then raise the prices astronomically [for a] temporary period of time before other competitors enter the market."[25]

209. To placate Congress, Valeant's CEO testified to the U.S. Senate on April 27, 2016 that "it was a mistake to pursue, and in hindsight I regret pursuing, transactions where a central premise was a planned increase in the prices of the medicines."[26] And he gave them the false comfort that, going forward, "[w]e expect our pricing actions to track industry norms."[27]

210. In fact, at that precise moment, Valeant was continuing to adhere to the unlawful agreements that extended the Glumetza monopoly. Two months earlier, in February 2016, Lupin finally entered the market with generic Glumetza, having unlawfully agreed to stay out of the market from May 2012 until February 2016.

211. By then, Valeant's ruthless exploitation of the Glumetza monopoly had raised the price of the branded product astronomically. And when Lupin entered the market, Valeant adhered to the unlawful agreement by refraining from marketing an authorized generic.

212. The direct result of that unlawful adherence was that Lupin, as the only generic available, was able to price its generic at a substantially smaller discount off the brand price than it otherwise would have and could also take advantage of the gigantic price increases for Glumetza that Defendants engineered. Lupin's agreement to delay entry by four years had allowed Valeant to

---

[23] House Comm. On Oversight and Government Reform Memorandum, Documents Obtained by Committee from Valeant Pharmaceuticals (Feb. 2, 2016), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf.

[24] Developments in the Prescription Drug Market: Oversight Hearing Before the House Comm. On Oversight and Government Reform, 114 Cong., at 3, 119 (Feb. 4, 2016), available at https://www.govinfo.gov/content/pkg/CHRG- 114hhrg25500/pdf/CHRG-114hhrg25500.pdf.

[25] *Id.*

[26] Statement of J. Michael Pearson before the Senate Special Committee on Aging (Apr. 27, 2016), https://www.aging.senate.gov/imo/ media/doc/SCA_Pearson_4_27_16.PDF.

[27] *Id.*

raise the brand price by nearly 800%. Now Valeant was adhering to the unlawful agreement by not marketing an authorized generic, which would have driven the generic price down to approximately a 48% discount off the brand. While Valeant was making false assurances to Congress that Valeant had reformed its corporate ways, it was both keeping its brand price at the monopoly-enabled level and depriving purchasers of the generic competition that would have cut then-current prices in half.

213. As a result, throughout 2016 purchasers of Glumetza were paying more than $3,000 per month for the brand product and more than $2,200 per month for Lupin's generic. Compare those prices to what would have happened if Defendants had not entered into their unlawful agreements: Lupin would have entered the market in 2012, Assertio and Santarus would have immediately entered the market with an authorized generic, and later, both Sun and Watson would have brought their generics to market.

214. In 2012, the price of a 30-day supply of 1,000 mg branded Glumetza was about $250. By the beginning of 2015, long before Valeant got its hands on the product and jacked up prices by more than 750%, the generics would have taken almost all of the unit sales and would have competed the price down to a fraction of the 2012 price.

215. As a result of the delay in generic entry and Defendants' exploitation of the monopoly that they created, only brand Glumetza was available in 2015. The result was that the 30-pill price after Valeant's increase was more than $3,000 rather than a very small percentage thereof. Lupin belatedly entered the market in 2016. But the combined effect of the astronomical brand price and Valeant's agreement not to market an authorized generic was that Lupin's price for a 30-day supply of the generic product was more than $2,200 rather than a very small percentage thereof.

216. According to GoodRx.com, a 30-day supply of the 1,000 mg generic product presently – now that Watson and Sun's generic products have been on the market for several quarters – sells for approximately $370.[28] This represents a significant decline from the $2,200

[28] https://www.goodrx.com/metformin-er-glumetza?dosage=500mg&form=tablet&label_override=metformin+ER+%28Glumetza%29&quantity=30. The generic product currently sells for approximately 11% of the price of the brand drug.

price Lupin charged for a 30-day supply of its 1,000 mg generic product during its period of exclusivity.

217. Altogether, Defendants' unlawful extension of the Glumetza monopoly has already caused end payors to overpay by more than hundreds of millions, if not billions of dollars, and continues to result in substantial overcharges to class members.

218. On May 15, 2017, Teva Pharmaceutical Industries Ltd. (which had acquired Watson) began marketing its generic 500 mg and 1,000 mg Glumetza products. On July 25, 2018, Sun began marketing its generic 500 mg and 1,000 mg Glumetza products. Watson and Sun had received licenses from Assertio/Santarus to enter the market no earlier than August 2016. The reasons for their delays after August 2016 are currently unknown to Plaintiff.

219. Defendants' anticompetitive No-AG Agreement, MFE, and MFEP caused Watson and Sun to agree to delay entry until after August 2016, with the result that they put development of their generic Glumetza on hold. If Defendants had not caused Watson and Sun to agree to delay entry until after August 2016, they would have resolved any technical or other delay-inducing issues much sooner (or never would have encountered them to begin with), and would have entered the market before July 2015, on a date to be determined by the jury.

VI. THE ANTICOMPETITIVE EFFECTS ON INTERSTATE AND INTRASTATE COMMERCE

220. During the relevant time period, Defendants manufactured, sold, and shipped Glumetza and generic Glumetza across state lines, and within state lines, in an uninterrupted flow of interstate and intrastate commerce.

221. During the relevant time period, Plaintiff and members of the Classes purchased, paid, and/or provided reimbursement for some or all of the purchase price of Glumetza or its AB-rated generic equivalents from Defendants. As a result of Defendants' illegal conduct, Plaintiff and members of the Classes did so at artificially inflated prices for Glumetza and generic Glumetza.

222. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged

herein, within the flow of, and substantially affecting, interstate commerce, including within this District.

VII. MONOPOLY POWER AND MARKET DEFINITION

223. The relevant product market is metformin hydrochloride extended release tablets in 500 mg and 1,000 mg strengths, including branded Glumetza and its bioequivalent (*i.e.*, AB-rated) generic versions of Glumetza. The relevant geographic market is the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

224. Direct evidence of Defendants' monopoly power includes, *inter alia*, the following: (a) absent Defendants' unlawful conduct, generic Glumetza would have entered the market much earlier at a substantial discount to brand Glumetza; (b) when generic Glumetza eventually entered the market, it quickly took a substantial portion of brand Glumetza's unit sales; (c) Defendants' gross margin on Glumetza (including the costs of ongoing research, development, and marketing) at all relevant times was in excess of 70%; (d) Defendants never lost Glumetza sales or lowered the price of Glumetza to the competitive level in response to the pricing of other brand or generic drugs except AB-rated generic Glumetza; (e) from 2012 to 2015, Defendants profitably raised the price of Glumetza by over 40%; and (f) in 2015, Defendants profitably raised the price of Glumetza by over 750%.

225. Defendants' power to profitably raise these prices above the competitive level results in substantial part from a significant imperfection in the United States marketplace for prescription pharmaceuticals. Branded drug manufacturers can exploit this imperfection to obtain or maintain market power.

226. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the product choice and the payment obligation, the product's price plays an appropriate role in the person's choice and, consequently, manufacturers have an appropriate incentive to reduce their prices to the competitive level.

227. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many

pharmaceutical products, including Glumetza, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer).

228. Brand manufacturers, such as Santarus, Salix, and Valeant, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

229. A small but significant non-transitory price increase above the competitive level for Glumetza by Defendants would not cause a loss of sales sufficient to make the price increase unprofitable.

230. Other drugs that are not AB-rated to Glumetza cannot be substituted automatically for Glumetza by pharmacists and do not exhibit substantial cross-price elasticity of demand with respect to Glumetza. Thus, they are not economic substitutes for, nor reasonably interchangeable with, Glumetza.

231. Pharmaceutical products with metformin hydrochloride extended release as the active ingredient have pharmacological properties that differentiate them from other drugs for treating Type 2 diabetes. Brand Glumetza is therapeutically differentiated from all diabetes products other than AB-rated generic versions of Glumetza. The existence of other products indicated for the treatment of Type 2 diabetes has not significantly constrained Defendants' pricing of Glumetza and/or generic Glumetza.

232. In general, Glumetza is considered the first-choice medication for the treatment of Type 2 diabetes and is not reasonably interchangeable with other Type 2 diabetes drugs. In part, this is the result of metformin's long-term safety profile, which is not available for many newer Type 2 diabetes drugs such as DPP-4 inhibitors. Glumetza also has better cardiovascular mortality

than sulfonylurea drugs used to treat Type 2 diabetes. Glumetza is also considered weight neutral or helps people lose weight.

233. Glumetza is not therapeutically interchangeable with metformin products that are not extended-release. Metformin can cause gastrointestinal side effects, which can be reduced by taking an extended-release form. Additionally, extended-release forms of metformin can reduce the daily dosing to a single once-a-day pill providing a simpler dosing regimen. The differing efficacy, dosing, safety and side-effect profiles of different oral Type 2 diabetes drugs play a critical role in doctors' selection of the most appropriate form of the drug for each patient, and a patient's compliance with taking an oral Type 2 diabetes drug is improved with one that requires fewer doses and that the patient can better tolerate.

234. Glumetza is also not reasonably interchangeable with other extended-release forms of metformin, such as Glucophage XR and Fortamet. This non-interchangeability arises from, among other reasons, the way that different patients react to the products' varying release mechanisms.

235. Specifically, a substantial number of doctors perceive Glumetza to offer the possibility of reduced gastrointestinal side effects for patients, compared to other extended-release metformin products. Glumetza uses a polymer delivery technology that expands from stomach fluid, preventing the pill from moving into the intestine. The stomach fluid then dissolves and releases the metformin over a period of 8 to 10 hours. The dissolved metformin is thus mixed, over time, with other contents of the patient's stomach and transported into the duodenum, where it is absorbed.

236. This process results in some substantial number of doctors concluding that Glumetza may cause fewer gastrointestinal side effects than other extended-release metformin products. Assertio, Santarus, Salix, Valeant, Bausch, and PDL differentiated Glumetza from extended-release metformin products in their marketing, on the ground that it retains metformin in the patient's stomach, allowing for constant multi-hour flow of the drug into the gastrointestinal tract. And they asserted that this technology offered patients a significantly enhanced opportunity for increased absorption of the drug. They touted to investors and others that "physicians are receptive to

Glumetza's differentiating features of controlled delivery and GI tolerability."[29] Moreover, the extended-release mechanism dissolves at the end of its useful life and is passed through the gastrointestinal tract and eliminated.

237. In contrast, for example, another extended-release metformin prescription drug—Fortamet—delivers metformin throughout the entire gastrointestinal tract. Fortamet tablets have a membrane surrounding the metformin, and the membrane has two laser-drilled holes. Water is taken into the holes and dissolves the metformin inside, and the dissolved drug is released through those holes at a constant rate all the time that the pill is moving through the small intestine. Some substantial number of doctors conclude, therefore, that Fortamet has a higher likelihood of causing gastrointestinal side effects. Patients typically will see the pill's shell in their stool.

238. Very substantial decreases in the price of other extended-release metformin products did not constrain the price of brand Glumetza to the competitive level. For example, generic Fortamet entered the market in 2012, substantially driving down the average price of a Fortamet pill (weighted average of brand and generic price). Despite that substantial price decrease, from 2012 to mid-2015 the quarterly unit sales of Glumetza increased while the price increased more than 40%. The percentage increase in Glumetza net revenue (net of all discounts, rebates, etc.) was at least that great.

239. A generic version of another extended-release metformin product—Glucophage XR—has been available since 2005. That product's extended-release mechanism is similar to Fortamet's and dissimilar to Glumetza's. Yet from 2012 through mid-2015 Glumetza had the sales, price, and net revenue gains described above.

240. Neither Glucophage XR (brand or generic) nor Fortamet (brand or generic) prevented the nearly 800% price increase in Glumetza in 2015. That price increase was enormously profitable for Valeant. The dollar sales of brand Glumetza for the third and fourth quarters of 2015 (after the price increase but before Lupin's entry) were more than $800 million; the sales in the prior two quarters were less than $145 million.

[29] *See* Santarus' May 8, 2012 Earnings Call with Investors.

241. Defendants needed to control only Glumetza and its AB-rated generic equivalents, and no other products, to maintain the price of Glumetza and Glumetza generics profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions of Glumetza would render Defendants unable to maintain their supracompetitive prices of Glumetza without losing substantial sales.

242. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

243. During the relevant time, Defendants had monopoly power in the market for Glumetza and AB-rated generic substitutes because they had the power to exclude competition and/or raise or maintain the price of Glumetza to supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

244. Until May 15, 2017, at all relevant times, Defendants' market share in the relevant market was at or near 100%. Before other generics entered the market, Glumetza had annual sales in excess of $1 billion.[30]

VIII. CLASS ACTION ALLEGATIONS

245. Plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of the following classes (the "Classes"):

The Injunction Class

All persons and entities that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Glumetza or its AB-rated generic equivalents from a Defendant beginning at least as early as May 6, 2012 until the effects of Defendants' conduct cease (the "Class Period"), anywhere in the United States.

The Damages Class

[30] https://www.tevapharm.com/news/teva_announces_launch_of_generic_glumetza_in_the_united_states_05_17.aspx..

> All persons and entities that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Glumetza or its AB-rated generic equivalents from a Defendant beginning at least as early as May 6, 2012 until the effects of Defendants' conduct cease (the "Class Period"), in the District of Columbia, Puerto Rico, or any of the following states and commonwealths: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, or Wyoming.

246. The following persons and entities are excluded from each of the above-described, proposed Classes:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

b. Governmental entities, except for government-funded employee benefit plans;

c. All persons or entities who purchased Glumetza for purposes of resale or directly from Defendants or their affiliates;

d. Fully-insured health plans (*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

e. "Single flat co-pay" consumers who purchase Glumetza only via fixed dollar co-payment that does not vary on the basis of the purchased drug's status as branded or generic (*e.g.*, $20 for both branded and generic drugs); and

f. The judges in this case and any members of their immediate families.

247. Members of the Classes are so numerous and geographically dispersed that joinder of all members of the Classes is impracticable. Plaintiff believes that there are thousands of members of the Classes widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together.

248. Plaintiff's claims are typical of the claims of members of the Classes. Plaintiff and members of the Classes were harmed by the same wrongful conduct by Defendants in that they paid artificially inflated prices for branded and generic Glumetza and were deprived of the benefits of earlier and more robust competition from less-expensive generic equivalents of Glumetza as a result of Defendants' wrongful conduct.

249. Plaintiff will fairly and adequately protect and represent the interests of the members of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

250. Plaintiff is represented by counsel with experience in the prosecution of class antitrust litigation with expertise in class antitrust litigation involving pharmaceutical products.

251. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to both Classes. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

252. Questions of law and fact common to the Classes include:

a. Whether Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. Whether there exist any legitimate procompetitive reasons for some or all of Defendants' conduct;

c. To the extent any such procompetitive benefits exist, whether there were less restrictive means of achieving them;

d. Whether direct proof of Defendants' monopoly power is available and, if so, whether it is sufficient to prove the Defendants' monopoly power without the need to define the relevant market;

e. Whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

f. Whether Defendants' scheme, in whole or in part, caused antitrust injury through overcharges to Plaintiff and the members of the Classes;

g. Whether Defendants conspired to delay generic competition for Glumetza;

h. Whether, pursuant to the No-AG Agreement, Assertio/Santarus, Salix, Valeant, Bausch, and PDL's promise not to compete against Lupin's generic product constituted a large and unjustified payment;

i. Whether Defendants' No-AG Agreement was necessary to yield some cognizable, non-pretextual procompetitive benefit;

j. Whether the No-AG Agreement, MFE, and/or MFEP caused Sun, Watson, and/or other generic manufacturers to delay entry into the market;

k. Whether the MFE and MFEP were necessary to yield some cognizable, non-pretextual procompetitive benefit;

l. Whether Defendants' conduct created a bottleneck to further delay generic competition for Lupin;

m. Whether Defendants' conduct harmed competition;

n. Whether Defendants possessed the ability to control prices and/or exclude competition for Glumetza;

o. Whether Defendants' unlawful conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Glumetza; and

p. The quantum of overcharges paid by the Damages Class in the aggregate.

253. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in the management of this class action.

254. Plaintiff knows of no special difficulty to be encountered in litigation this action that would preclude its maintenance as a class action.

IX. DEFENDANTS' FRAUDULENT CONCEALMENT

255. A cause of action accrued for Plaintiff each time Plaintiff purchased, paid for, or reimbursed for a brand or generic Glumetza product at a supracompetitive price caused by Defendants' anticompetitive conduct. Each purchase, payment for, or reimbursement for brand or generic Glumetza at a supracompetitive price was the result of an overt act in furtherance of Defendants' continuing anticompetitive scheme. Other overt acts in furtherance of Defendants' continuing conspiracy include, but are not limited to, Lupin's refraining from entering the market until February 2016 and Valeant's refraining from marketing an authorized generic Glumetza until February 2017.

256. Due to Defendants' fraudulent concealment of their unlawful conduct, Plaintiff and members of the Damages Class are entitled to recover damages reaching back to the beginning of the Class Period (*i.e.*, May 6, 2012). Plaintiff and Class members had no knowledge of Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years before the filing of this Complaint.

257. Defendants' scheme was self-concealing, and Defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme.

258. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiff and members of the Classes. Defendants repeatedly made public reference to Lupin's agreement to delay entry until February 2016, but consistently, consciously, and actively omitted the fact that Lupin had agreed to that delayed date in exchange for a No-AG Agreement. For example:

a. In a May 8, 2012 filing with the Securities and Exchange Commission ("SEC"), Assertio included a redacted copy of its settlement agreement with Lupin. Assertio redacted all references to the No-AG Agreement. Based solely on information received and events occurring within the last four years, Plaintiff now believes that the redacted agreement refers to the No-AG Agreement as follows:

> "Section 3.5. [***]

Section 3.6. [***] Notwithstanding the provisions of Sections 3.4 and 3.5, Depomed and Santarus shall have the right to: [***]"

b. On March 27, 2012, pursuant to their settlement Assertio and Lupin asked the Court to enter a consented-to injunction in the patent litigation. Those Defendants falsely represented to this Court—and placed on the public record—that the terms of their settlement were in "good faith," "serve the public interest," were "procompetitive," and "benefit … the parties and consumers alike." Consent Injunction and Dismissal Order, *Depomed, Inc. v. Lupin Pharms., Inc.*, et al., No. 4:09-cv-05587-PJH, ECF No. 152, at p.1 (N.D. Cal. Mar. 27, 2012). Those Defendants affirmatively advised the Court and the public of the agreed entry date of February 1, 2016 but omitted all references to the No-AG Agreement. *See id.* at 5(a).

c. In the following SEC filings, Santarus affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Agreement: Santarus Inc., Annual Report (Form 10-K) at 24 (March 5, 2012); Santarus Inc., Quarterly Report (Form 10-Q) at 12 (May 5, 2012); Santarus Inc., Quarterly Report (Form 10-Q) at 12 (August 7, 2012); Santarus Inc., Quarterly Report (Form 10-Q) at 12 (November 8, 2012); Santarus Inc., Quarterly Report (Form 10-Q) at 34 (November 7, 2013); Santarus Inc., Quarterly Report (Form 10-Q) at 13 (May 6, 2013); Santarus Inc., Quarterly Report (Form 10-Q) at 14 (August 6, 2013).

d. In the following SEC filings Salix affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Agreement: Salix, Pharmaceuticals, Ltd., Annual Report (Form 10-K) at 9 (March 1, 2013); Salix, Pharmaceuticals, Ltd., Annual Report (Form 10-K) at 7 (February 28, 2014).

e. In addition to the May 8, 2012 SEC filing discussed above, in the following SEC filings Assertio (formerly known as Depomed, Inc.) affirmatively referred to the references to the No-AG Agreement: Inc., Annual Report (Form 10-K) at 5 (March 8, 2012); Depomed Inc., Quarterly Report (Form 10-Q) at 22 (August 3, 2012); Depomed Inc., Quarterly Report (Form 10-Q) at 24 (November 5, 2012); Depomed

Inc., Quarterly Report (Form 10-Q) at 21 (November 9, 2013); Depomed Inc., Quarterly Report (Form 10- Q) at 21 (August 8, 2013); Depomed Inc., Quarterly Report (Form 10-Q) at 23 (November 7, 2013).

f. In a call with stock analysts on May 8, 2012, Assertio affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Agreement.

g. In a press release dated May 8, 2012, Santarus affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Agreement.

h. In calls with stock analysts on November 7, 2013 and January 16, 2014, Salix affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Agreement.

i. In a call with stock analysts on October 27, 2015, Lupin affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Agreement.

259. Defendants did not publicly disclose the No-AG Agreement until doing so suited their interests. Specifically, Lupin, on a February 5, 2016 call with stock analysts – just days after it launched its generic version of Glumetza under its agreement with Assertio and Santarus – disclosed the No-AG Agreement in an effort to pump up the value of its stock. To emphasize that it would make extraordinary profits on the sale of Glumetza, Lupin revealed publicly for the first time that its agreement with Assertio and Santarus included the No-AG Agreement.

260. On that call, Vinita Gupta, Lupin's CEO, stated:

> A: Glumetza is a different story. We have six months exclusivity on Glumetza after which I believe some has a tentative and there is another product filing that we – I think its Actavis [Watson] again that has a filing. So, we would expect a couple of competitors, so it probably will be a four player market after the six-month exclusivity is done including the brand. The brand Valeant has

> the deal with Walgreens. So, we would expect perhaps after the six months, they will be competing as well.
>
> Q: Okay. And on Glumetza, right now the, but there is no AG on the – that Valeant has come up with?
>
> A: No. ***We have [an] AG free launch. So, we know that the six months, there would be no AG.***

261. Plaintiff filed this Complaint within four years of the first public revelation of the No-AG Agreement.

262. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by Defendants, Plaintiff and members of the Classes had no knowledge of the scheme and conspiracy until within four years of the filing of this Complaint; they did not have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed; and if they would have had the facts or information to cause them to conduct an investigation, any such investigation would not have revealed the existence of Defendants' unlawful conspiracy.

263. Plaintiff and members of the Classes lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of Plaintiff and members of the Classes would not have uncovered those facts until within four years of the filing of this complaint.

264. The partially redacted settlement agreement that Assertio included in its May 8, 2012 SEC filing revealed the existence of an MFE. It also revealed an outline of what may be the MFEP, but did not include the MFEP's essential terms. Plaintiff learned of the MFEP's essential terms, and in the exercise of reasonable diligence could have learned of them, only through information gained and events occurring within the last four years.

265. Plaintiff does not allege that the MFE or MFEP, alone or together with each other, is unlawful. As alleged in detail above, the MFE and MFEP prevented later filers from unraveling the

anticompetitive effects of the No-AG Agreement. That is, Plaintiff alleges that the MFE and MFEP are anticompetitive in the context of an unlawful conspiracy of which the No-AG Agreement is the centerpiece. Plaintiff became aware of that context, and in the exercise of reasonable diligence could have become aware of it, only after learning of the existence of the No-AG Agreement.

266. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's and members of the Classes' claims have been tolled.

X. CLAIMS FOR RELIEF

267. Defendants are jointly and severally liable for all damages suffered by Plaintiff and the Damages Class Members.

CLAIM I

Contract, Combination, and Conspiracy in Restraint of Trade Under the Sherman Act §1

Against All Defendants

268. Plaintiff incorporates the preceding paragraphs by reference.

269. At all relevant times, Defendants individually and/or collectively possessed substantial market power with respect to Glumetza and its AB-rated equivalents in the United States. Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

270. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

271. Defendants violated Section 1 of the Sherman Act, 15 U.S.C. §1, by entering into, adhering to, and/or enforcing an unreasonable restraint of trade, defined as Assertio, Santarus, Salix, Valeant, and Bausch's agreement with Lupin (and subsequently PDL) to implement a No-AG Agreement and related restraints on generic competition for Glumetza. The agreement, entered into on or about February 22, 2012, is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

a. delay entry of generic Glumetza and unlawfully extend the period in which brand Glumetza monopolized the relevant market;

b. delay entry of an authorized generic version of Glumetza until at least 180 days after Lupin's generic version of Glumetza entered the market;

c. delay the date that other generic manufacturers would enter the market; and

d. raise and maintain the prices that Plaintiff and Class Members would pay for Glumetza and its AB-rated equivalents at supra-competitive levels.

272. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the No-AG Agreement was not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraint's anticompetitive effects.

273. Individually and collectively, the value that Assertio and Santarus transferred and Lupin received under their agreement exceeded the costs of continued litigation or any arguably procompetitive benefits—and thus was "large and unjustified." Accordingly, the Assertio/Santarus and Lupin agreement is unlawful.

274. As a direct and proximate result of these Defendants' violation of Sherman Act §1, Plaintiff and the Class have been injured throughout the Class Period.

275. Plaintiff and the Injunction Class are entitled to injunctive relief and other equitable relief, pursuant to 15 U.S.C. §26.

CLAIM II

Monopolization Under the Sherman Act §2

Against All Defendants

276. Plaintiff incorporates the preceding paragraphs by reference.

277. At all relevant times, Defendants possessed substantial market power (*i.e.*, monopoly power) with respect to Glumetza and its AB-rated equivalents. Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

278. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

279. Defendants violated Section 2 of the Sherman Act, 15 U.S.C. §2, by monopolizing and conspiring to monopolize the market for Glumetza and its AB-rated equivalents in the United States.

280. As alleged herein, Defendants willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than using greater business acumen.

281. Defendants' conscious objective was to further their dominance through exclusionary conduct.

282. As described further above, Defendants knowingly, willfully and wrongfully maintained monopoly power and harmed competition for Glumetza and its AB-rated equivalents by entering into a No-AG Agreement and other agreements designed to thwart generic competition, including entering into and abiding by MFE and MFEP agreements.

283. Defendants' anticompetitive conduct is exclusionary conduct the purpose and effect of which is to willfully maintain monopoly power, which harms consumers, third party payors, and competition. Even if Defendants were able to assert some justification for their conduct, such conduct is and was broader than necessary to achieve such a purpose.

284. As a direct and proximate result of these Defendants' violation of §2 of the Sherman Act, Plaintiff and the Class have been injured throughout the Class Period.

285. Plaintiff and the Injunction Class are entitled to injunctive and other equitable relief, pursuant to 15 U.S.C. §26.

CLAIM III

Conspiracy and Combination in Restraint of Trade Under State Law

Against All Defendants

286. Plaintiff incorporates the preceding paragraphs by reference.

287. Defendants' conduct, as described above, violated the following state antitrust laws:

a. Ariz. Rev. Stat. §44-1401, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Arizona by the Damages Class Members;

b. Cal. Bus. Code §16700, *et seq.*, and Cal. Bus. Code §§17200, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in California by the Damages Class Members;

c. Conn. Gen. Stat. §35-24, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Connecticut by the Damages Class Members;

d. D.C. Code Ann. §28-4501, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in the District of Columbia by the Damages Class Members;

e. Hawaii Code §480, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Hawaii by the Damages Class Members;

f. 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Illinois by the Damages Class Members;

g. Iowa Code §553 *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Iowa by the Damages Class Members;

h. Kan. Stat. Ann. §50-101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Kansas by Damages Class Members;

i. Me. Rev. Stat. Ann. 10, §1101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Maine by the Damages Class Members;

j. Mich. Comp. Laws Ann. §445.772, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Michigan by the Damages Class Members;

k. Minn. Stat. §325D.49, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Minnesota by the Damages Class Members;

l. Miss. Code Ann. §75-21-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Mississippi by members of the Damages Class Members;

m. Neb. Code Ann. §59-801, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Nebraska by the Damages Class Members;

n. Nev. Rev. Stat. Ann. §598A, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Nevada by the Damages Class Members;

o. N.H. Rev. Stat. Ann. §356:1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New Hampshire by the Damages Class Members;

p. N.M. Stat. Ann. §57-1-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New Mexico by the Damages Class Members;

q. N.Y. Gen. Bus. L. §340, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New York by the Damages Class Members;

r. N.C. Gen. Stat. §75-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in North Carolina by the Damages Class Members;

s. N.D. Cent. Code §51-08.1-01, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in North Dakota by the Damages Class Members;

t. Or. Rev. Stat. §6.46.705, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Oregon by the Damages Class Members;

u. S.D. Codified Laws Ann. §37-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in South Dakota by the Damages Class Members;

v. Tenn. Code Ann. §47-25-101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Tennessee by the Damages Class Members;

w. Utah Code Ann. §76-10-3101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Utah by Damages Class Members who are either citizens or residents of Utah;

x. Vt. Stat. Ann. 9, §2453, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Vermont by the Damages Class Members;

y. W.Va. Code §47-18-3, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in West Virginia by the Damages Class Members; and

z. Wis. Stat. §133.03, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Wisconsin by the Damages Class Members.

288. Plaintiff and the Damages Class Members seek damages as permitted by law for the injuries they suffered as a result of these Defendants' anticompetitive conduct.

CLAIM IV

Monopolization and Monopolistic Scheme Under State Law

Against All Defendants

289. Plaintiff incorporates the preceding paragraphs by reference.

290. Defendants' conduct, as described above, violated the following state antitrust laws:

a. Ariz. Rev. Stat. §44-1401, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Arizona by the Damages Class Members;

b. Cal. Bus. Code §16700, *et seq.*, and Cal. Bus. Code §17200, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in California by the Damages Class Members;

c. Conn. Gen. Stat. §35-24, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Connecticut by the Damages Class Members;

d. D.C. Code Ann. §28-4501, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in the District of Columbia by the Damages Class Members;

e. Hawaii Code §480, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Hawaii by the Damages Class Members;

f. 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Illinois by the Damages Class Members;

g. Iowa Code §553 *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Iowa by the Damages Class Members;

h. Kan. Stat. Ann. §50-101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Kansas by Damages Class Members;

i. Me. Rev. Stat. Ann. 10, §1101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Maine by the Damages Class Members;

j. Mich. Comp. Laws Ann. §445.772, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Michigan by the Damages Class Members;

k. Minn. Stat. §325D.49, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Minnesota by the Damages Class Members;

l. Miss. Code Ann. §75-21-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Mississippi by members of the Damages Class Members;

m. Neb. Code Ann. §59-801, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Nebraska by the Damages Class Members;

n. Nev. Rev. Stat. Ann. §598A, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Nevada by the Damages Class Members;

o. N.H. Rev. Stat. Ann. §356:1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New Hampshire by the Damages Class Members;

p. N.M. Stat. Ann. §57-1-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New Mexico by the Damages Class Members;

q. N.Y. Gen. Bus. L. §340, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New York by the Damages Class Members;

r. N.C. Gen. Stat. §75-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in North Carolina by the Damages Class Members;

s. N.D. Cent. Code §51-08.1-01, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in North Dakota by the Damages Class Members;

t. Or. Rev. Stat. §6.46.705, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Oregon by the Damages Class Members;

u. S.D. Codified Laws Ann. §37-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in South Dakota by the Damages Class Members;

v. Tenn. Code Ann. §47-25-101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Tennessee by the Damages Class Members;

w. Utah Code Ann. §76-10-3101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Utah by Damages Class Members;

x. Vt. Stat. Ann. 9, §2453, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Vermont by the Damages Class Members;

y. W.Va. Code §47-18-3, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in West Virginia by the Damages Class Members; and

z. Wis. Stat. §133.03, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Wisconsin by the Damages Class Members.

291. Plaintiff and the Damages Class Members seek damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

CLAIM V

State Consumer Protection Violations

(Against All Defendants)

292. Plaintiff incorporates the preceding paragraphs by reference.

293. Defendants engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and the Damages Class Members were deprived of the opportunity to purchase generic versions of Glumetza and were forced to pay higher prices for branded and generic versions of Glumetza.

294. There is gross disparity between the price that Plaintiff and the Damages Class Members paid for Glumetza and generic versions of Glumetza compared to what they would have paid for less expensive generic versions of Glumetza, which should and would have been available sooner but for Defendants' unlawful conduct.

295. By engaging in the foregoing conduct, Defendants have engaged in unfair competition and/or unfair and/or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Arkansas by members of the Class.

b. Ariz. Code §§ 44-1255, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Arizona by members of the Class.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in California by members of the Class.

d. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in the District of Columbia.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Florida by members of the Class.

f. Idaho Code §§ 48-601, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Idaho by members of the Class.

g. 815 ILCS §§ 505/1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Illinois by members of the Class.

h. 5 Me. Rev. Stat. §§ 205-A, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Maine by members of the Class.[31]

i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Massachusetts by members of the Class.[32]

j. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Michigan by members of the Class.

k. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Minnesota by members of the Class.

---

[31] Pursuant to 5 M.R.S.A. §213(1-A), Plaintiff sent pre-lawsuit, written demand letters to Defendants.

[32] Pursuant to M.G.L.A. 93A §9(3), Plaintiff sent pre-lawsuit, written demand letters to Defendants.

l. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Missouri by members of the Class.

m. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Nebraska by members of the Class.

n. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Nevada by members of the Class.

o. N.H. Rev. Stat. §§ 358-A, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New Hampshire by members of the Class.

p. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New Mexico by members of the Class.

q. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in New York by members of the Class.

r. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in North Carolina by members of the Class.

s. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Oregon by members of the Class.

t. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Pennsylvania by members of the Class.

u. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Rhode Island by members of the Class

v. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in South Dakota by members of the Class.

w. Utah Code §§13-11-1, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Utah by member of the Class.

x. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in Virginia by members of the Class.

y. West Virginia Code §§ 46A-6-101, *et seq.*, with respect to purchases, payments, or reimbursements for some or all of the purchase price, of Glumetza or its AB-rated generic equivalents in West Virginia by members of the Class.

CLAIM VI

Unjust Enrichment

(Against All Defendants)

296. Plaintiff incorporates by reference the preceding allegations.

297. Defendants have benefited from monopoly profits on the sale of Glumetza resulting from the unlawful and inequitable acts alleged herein.

298. Defendants' financial benefit resulting from their unlawful and inequitable acts is traceable to overpayments for Glumetza by Plaintiff and members of the Damages Class.

299. Plaintiff and the Damages Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Damages Class.

300. It will be futile for Plaintiff and the Damages Class to seek a remedy from any party with whom they have privity of contract.

301. It would be futile for Plaintiff and the Damages Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it/they indirectly purchased Glumetza, as they are not liable and would not compensate Plaintiff and the Damages Class for unlawful conduct caused by Defendants.

302. The economic benefit of overcharges and monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for brand and generic Glumetza is a direct and proximate result of Defendants' unlawful practices.

303. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Damages Class, as Plaintiff and the Damages Class paid anticompetitive and monopolistic prices during the Class Period, inuring to Defendants' benefit.

304. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Defendants to be permitted to retain any of the overcharges for brand or generic Glumetza derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged herein.

305. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Damages Class.

306. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Damages Class all unlawful or inequitable proceeds they received.

307. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Damages Class.

308. Plaintiff and the Damages Class have no adequate remedy at law.

XI. DEMAND FOR JUDGMENT

309. Accordingly, Plaintiff, on behalf of itself and the proposed Classes, respectfully demands that the Court:

a. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, and direct that

reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and declare Plaintiff as the representative of the Classes;

b. Enter joint and several judgments against the Defendants and in favor of Plaintiff and the Classes;

c. Enjoin Defendants from their ongoing illegal, anticompetitive misconduct;

d. Award the Damages Class damages, and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial;

e. Grant Plaintiff and the Classes equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

f. Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees, as provided by law; and

g. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

310. Pursuant to Fed. R. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

Dated: September 18, 2019

Respectfully submitted:

By: */s/ Whitney E. Street*

Whitney E. Street (California Bar No. 223870)
BLOCK & LEVITON LLP
100 Pine Street, Suite 1250
San Francisco, CA 94111
Tel.: (415) 968-1852
wstreet@blockesq.com

Stephen J. Teti (*pro hac vice motion forthcoming*)
BLOCK & LEVITON LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
Tel.: (617) 398-5600
steti@blockesq.com

Counsel for Plaintiff